EXHIBIT B

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO** **WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXPERT REPORT OF SCOTT GUELCHER, PH.D.

The opinions which are held and expressed to a reasonable degree of scientific certainty are as follows:

I. QUALIFICATIONS

Scott Guelcher, Ph.D.

I received my Bachelor's Degree in Chemical Engineering from Virginia Tech in 1992, my Master's Degree in Chemical Engineering from the University of Pittsburgh in 1996, and my Ph.D. in Chemical Engineering from Carnegie Mellon University in 1999. I completed my training as a Post-Doctoral Research Associate in Biomedical Engineering at Carnegie Mellon University in 2005.

I have been an Associate Professor in the Department of Chemical and Biomolecular Engineering at Vanderbilt University since 2012, and prior to that I was an Assistant Professor Department of Chemical and Biomolecular Engineering at Vanderbilt from 2005 through 2012. I was recently appointed a Chancellor's Faculty Fellow for the period 2015 – 2017. In 2015, I taught Process Design and will teach Introduction to Engineering in Fall 2016.

My professional experience includes: Associate Scientist and Senior Associate Scientist at Bayer Corporation, Polyurethanes Division, in South Charleston, West Virginia from 1999-2003; Trainee at Philips Research, in Eindhoven, The Netherlands in 1998; Limited Service Employee at Eastman Chemical Co. from 1995-1997; and Chemical Engineer at Eastman Chemical Co. from 1992-1994.

I am a co-editor of the book, *An Introduction to Biomaterials,* SA Guelcher and JO

Hollinger, eds., Boca Raton: CRC Press 2006. I am also the author of 9 book chapters, including, but not limited to, SA Guelcher, Polyurethanes. In *An Introduction to Biomaterials*, 161 – 183. SA Guelcher and JO Hollinger, eds. Boca Raton, CRC Press 2006; SA Guelcher, Biocompatibility of Injectable Materials. In *Injectable Biomaterials: Science and Applications*. B Vernon, ed. Woodhead Publishing 2011; EM Prieto and SA Guelcher, Tailoring Properties of Polymeric Biomedical Foams. *In Biomedical Foams for Tissue Engineering Applications*. P Netti, ed. Woodhead Publishing 2014; and S. Fernando, M McEnergy, and SA Guelcher, Polyurethanes for Bone Tissue Engineering. In Advances in Polyurethane Biomaterials. J Guan and S Cooper, eds. Woodhead Publishing 2016. My areas of research and interest include biomaterials design and development, drug and gene delivery, tissue engineering, and *in vitro* models for cancer metastasis.

My experience, education and training and a complete list of my published articles are summarized in my Curriculum Vitae attached to this report as Exhibit A. I have published 74 peer-reviewed articles, including two on the design of scaffolds that degrade in response to secretion of reactive oxygen species by infiltrating cells and one on degradation of explanted pelvic mesh. I have given 52 invited presentations and co-authored 176 abstracts presented at scientific meetings, two of which relate to oxidation of polypropylene in biomedical devices. I am a co-inventor on 9 issued U.S. and European Patents and 20 pending applications.

II. SUMMARY OF OPINIONS

This report is an examination and assessment of the polypropylene mesh utilized in devices manufactured by Ethicon to treat Stress Urinary Incontinence (SUI) and pelvic organ prolapse (POP). All of the opinions presented herein are made to a reasonable degree of scientific certainty and within my field of expertise.

1) Polypropylene reacts with molecular oxygen by autoxidation outside the body at elevated temperatures, resulting in chain scission and deterioration in its mechanical properties;

2) After implantation in the body, polypropylene reacts with reactive oxygen species secreted by inflammatory cells, resulting in oxidation, chain scission and mesh embrittlement;

3) The dynamic environment where the polypropylene mesh is implanted coupled with the foreign body reaction leads to oxidation, chain scission, reduction in molecular weight, embrittlement, degradation, flaking, pitting, and cracking;

4) The human body does not stop responding to an implanted mesh, or any frayed particles of mesh released during implantation, unless the product is removed in its entirety;

5) The mesh devices examined for this report are intended to last for the lifetime of the patient, but the presence of antioxidants does not permanently protect the PP against degradation, and thus it is not possible to guarantee that it will perform its intended function after implantation;

6) The effects of oxidation on the stability of Prolene were known to Ethicon prior to launching its SUI and POP devices, but the company did not consider the risks associated with polypropylene oxidation on the stability of Prolene mesh, to the detriment of patients implanted with the devices;

7) Polypropylene mesh is not inert and its properties change after implantation, which can lead to adverse events in an implantee; the use of heavy-weight meshes directly correlates with more exposure of polypropylene to the Foreign Body Reaction and greater changes after implantation, which increases the risk of complications.

III. BACKGROUND

Ethicon sells permanently implantable polypropylene-based meshes intended to treat Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP). All of the products in this litigation use the same Prolene resin to make the polypropylene-based meshes examined in this report.[1] Prolene was developed by Ethicon in the late 1960s for use as a suture material[2] and is more than 97% polypropylene. Additives are blended with polypropylene to modify its properties, including the antioxidants dilauralthiodipropionate (DLTDP) and Santonox-R to protect Prolene during high-temperature processing and long-term storage[3], and the blue pigment copper phthalocyanate (CPC) to enhance its visibility.[4] Prolene resin is manufactured as pellets, which are extruded into monofilaments that are subsequently knit into a specific mesh pattern.[5]

Ethicon's SUI devices consist of their instructions for use (IFU), insertion tools, and a high-density mesh (105 g/m^2) knit from Prolene monofilaments that are 6 mil (0.006 inches) in diameter.[6] The Prosima, Prolift, and Gynemesh POP devices all consist of their IFU, insertion tools, and a lower density mesh (45 g/m^2, known as Gynemesh[7]) knit from Prolene monofilaments that are 3.5 mil (0.0035 inches) in diameter.[8] The mesh used in the Prolift+M POP device is a hybrid material comprising a blend of absorbable Monocryl (poly(glycolide-*co*-ε-caprolactone)) and Prolene. After the Monocryl is absorbed, the density of the remaining Prolene mesh is 28 g/m^2.[9]

[1] Eth.Mesh.04941016; Eth.Mesh.01310578; Eth.Mesh.03987419; Eth.Mesh.07876572; Eth.Mesh.00019863; Eth.Mesh.0181699
[2] Eth.Mesh.02268619
[3] Eth.Mesh.02268619
[4] *Id.*
[5] ETH.MESH . 03987419; ETH.MESH.01310578
[6] Eth.Mesh.04941016
[7] ETH.MESH.01310578
[8] ETH.MESH.00074499
[9] *Id.*

IV. DISCUSSION

1) Polypropylene reacts with molecular oxygen outside the body by the process of autoxidation

Polypropylene (PP) is a plastic that is formed by a chemical reaction that joins the monomer propylene (which is composed of three carbon atoms and six hydrogen atoms) into a long repeating chain in a process called polymerization.[10] All forms of PP are susceptible to oxidation at the tertiary hydrogen-carbon bond.[11]

Oxidative attack at the tertiary hydrogen bond is the rate-controlling step in degradation process and results in the PP molecular chain being broken, a process known as chain scission, with the consequent loss in molecular weight. The mechanism of PP autoxidation is shown in Figure 1.[12] The process is autocatalytic, resulting in generation of more PP radicals (PP•) as the reaction progress. Thus, the reaction continues until no more PP can be broken down. The mechanism of PP autoxidation has been investigated extensively since the 1960s and was well known at the time that Ethicon was designing the mesh used in SUI and POP products. As shown in Figure 1, the products of autoxidation include shorter PP chains with carbonyl (C=O) and hydroperoxide (COOH) groups covalently bound to the PP. The presence of these groups can be detected by surface techniques such as

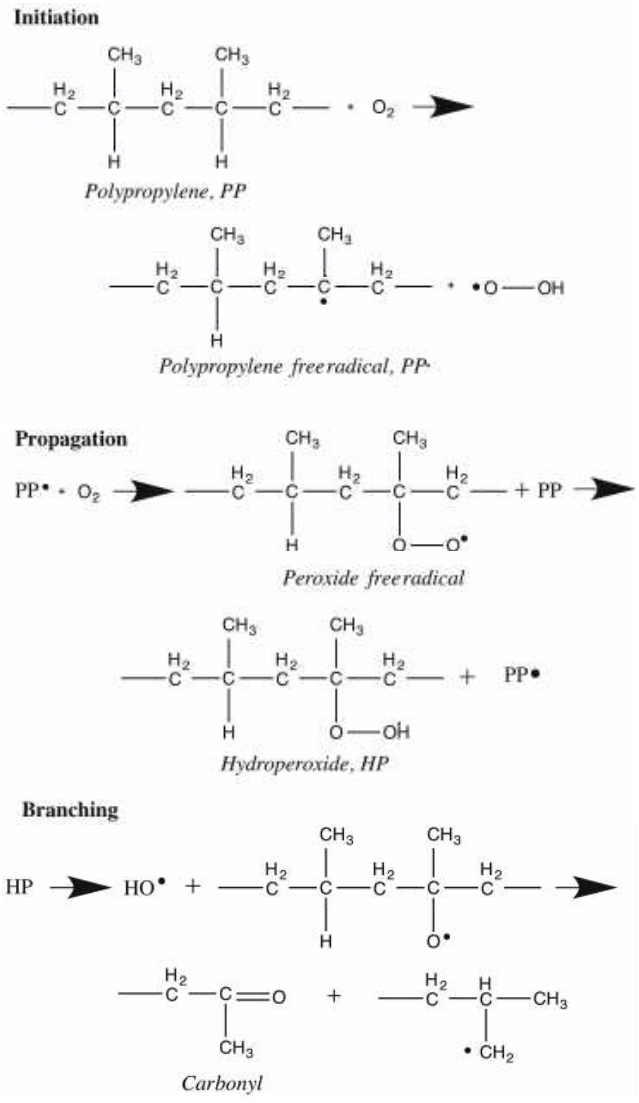

Figure 1. Mechanism of PP autoxidation. Initiation, propagation, and branching reactions lead to chain scission (loss of molecular weight). Products from autoxidation include hydroperoxide and carbonyl groups, which can be detected by analytical methods such as FTIR.

[10] Industrial Polymers, 2008, p. 74.
[11] H.H. Kausch. The effect of Degradation and Stabilization on the Mechanical Properties of Polymers Using Polypropylene Blends as the Main Example. Macromol. Symp. 2005, 225, 165-178.
[12] Reference for Figure 1: C Maier, T Calafut. Polypropylene: The Definitive User's Guide and Databook. Norwich, NY: Plastics Design Library, 1998.

FTIR and x-ray photoelectron spectroscopy (XPS) as evidence of oxidation.[13]

As shown in Figure 2, heat and UV radiation accelerate oxidation of PP.[14] Absorption of oxygen is diffusion-controlled, and the amor e the most accessible to diffusion of O_2. Th i- crystallizable segments of the PP chains a o neighboring crystalline domains. Since the tc e molecules, cutting of the tie molecules c r contributing to embrittlement. The key featur it of molecular weight loss that is critical for n Figure 3.[15] An important finding from this st r (~150 hours) than the induction time (~250 f carbonyl groups and hydroxyl groups associ r these conditions. Thus, the induction time overestimates the useful life of PP with respect to its mechanical properties.

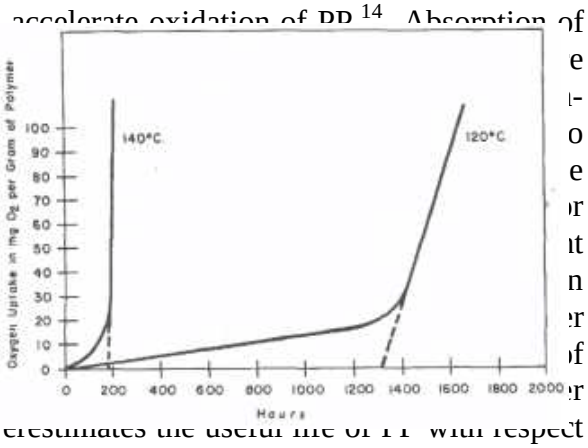

Figure 2. Autoxidation of PP is accelerated at elevated temperatures. Oxygen absorption of stabilized PP increases with time and temperature in 100% O_2. The induction time is determined by extrapolating the autocatalytic constant rate portion of the curve (steeper slope) to the x-axis (dashed line). Reproduced from Oswald and Turi 1965.[16]

The storage stability of unstabilized PP at ambient conditions has also been studied (Figure 4). When PP films were stored at room temperature and atmospheric O_2 concentration, the molecular weight (as measured by intrinsic viscosity) of PP dramatically decreased at 500 days (1.4 years). Thus, while oxidation is accelerated at elevated temperatures and oxygen concentrations (Figure 2), even at ambient temperature and atmospheric oxygen concentration there is chain scission and molecular weight loss.

2) After implantation in the body, polypropylene reacts with reactive oxygen species secreted by inflammatory cells, resulting in oxidation, chain scission and mesh embrittlement;

Liebert et al.[17] (1976) reported the oxidation of unstabilized PP filaments in vivo in a subcutaneous implantation model in hamsters. An induction time of 108 days was determined based on FTIR measurements of hydroxyl (which includes the hydroperoxide COOH) and carbonyl groups. FTIR measurements of hydroxyl and carbonyl groups showed behavior similar to that observed by Fayolle (Figure 3), consistent with the oxidation mechanism. However, Liebert estimated that the induction time for oxidation under *in vivo* conditions (37°C in 3.3% O_2) is approximately 20 years, which is dramatically higher than the measured value of 108 days. The authors suggested that enzymes or other chemicals secreted by cells accelerate the oxidation reaction. Recent papers have shown that this shorter induction time can be explained by the secretion of reactive oxygen species (ROS) by inflammatory cells near the PP fibers that oxidize and degrade the PP fibers *in vivo*.

[13] Fayolle et al. Oxidation-induced embrittlement in polypropylene – a tensile testing study. Polym Degrad Stability 70:333-40, 2000.
[14] HJ Oswald and E. Turi. The Deterioration of Polypropylene by Oxidative Degradation. Polymer Engineering and Science, 1965.
[15] Fayolle et al. Oxidation-induced embrittlement in polypropylene – a tensile testing study. Polym Degrad Stability 70:333-40, 2000.
[16] HJ Oswald and E. Turi. The Deterioration of Polypropylene by Oxidative Degradation. Polymer Engineering and Science, 1965.
[17] Liebert et al. Subcutaneous implants of PP filaments. JBMR 10:939-51, 1976

Upon implantation, the body recognizes PP mesh as a foreign body, which elicits an inflammatory response known as the foreign body reaction.[18] In the early stages, mononuclear cells migrate to the surface of the PP fibers, where they can adhere and participate in the events of the foreign body reaction (Figure 5). Adherent macrophages on the surface of the implanted biomaterial fuse to form foreign body giant cells (FGBCs). Adhesion of macrophages and FBGCs at the biomaterial surface results in an isolated microenvironment between the surface of the biomaterial and the plasma membrane of the cell.[19] In a process known as frustrated phagocytosis, macrophages and FBGCs secrete reactive oxygen species (ROS), acids, and enzymes into this micro-environment. Consequently, the surface of the biomaterial is exposed to high concentrations of ROS, and the chemical composition of the biomaterial will determine its susceptibility to oxidative degradation. As an example, the polyether soft segment of poly(ether urethane)s is known to undergo oxidative degradation. The morphological progression of the foreign body reaction on a poly(ether urethane) surface is shown in Figure 6.[9]

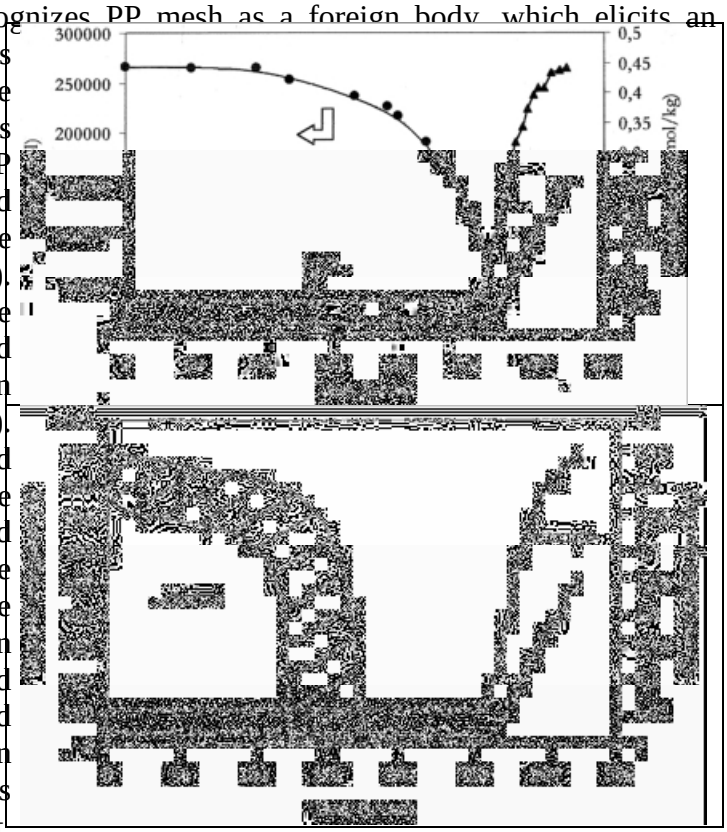

Figure 3. Degradation of unstabilized PP. (A) Molecular weight decreases with time when exposed to oxygen at elevated temperatures (Fayolle et al. 2000). On the right y-axis, the concentration of hydroxyl (triangles) and carbonyl (squares) groups are shown. (B) Evolution of ultimate elongation (diamonds) and hydroxyl (triangles) and carbonyl (squares) groups during exposure to oxygen at elevated temperatures (Fayolle et al. 2000).

[18] James M. Anderson, Analiz Rodriguez, and David T. Chang. Foreign Body Reaction to Biomaterials. Semin Immunol. 2008 April ; 20(2): 86–100.
[19] *Id.*

While initial studies identifying adherent macrophages and FBGCs as sources of ROS focused on poly(ether urethane)s, these cell populations have also been reported to infiltrate PP mesh.[20] In a recent study characterizing the foreign body reaction of PP implants in a rat abdominal wall model, macrophages and foreign body giant cells were observed both in the tissue surrounding the implant and also the implant itself.[21] Thus, within one week after implantation PP mesh was colonized by macrophages and FBGCs. Furthermore, PP mesh samples showed more inflammatory cells than PP sutures. The hernia literature also provides evidence that the foreign body reaction alters PP *in vivo*. In a study evaluating non-degradable meshes explanted from 17 patients that had surgery for repair of abdominal wall defects, a foreign body reaction characterized by granulation tissue and inflammatory cells 3 – 24 months post-implantation was seen.[22] The authors observed that inflammation near synthetic materials implanted in the abdominal wall persists for years. They further noted that this persistent foreign body reaction can lead to long-term complications, and that further studies are required to evaluate the long-term response of the host tissue to the implanted synthetic graft. Costello et al.[23] explanted PP hernia mesh and observed degradation of PP fibers with the oxidation of PP mediating cells during the foreign body reaction.

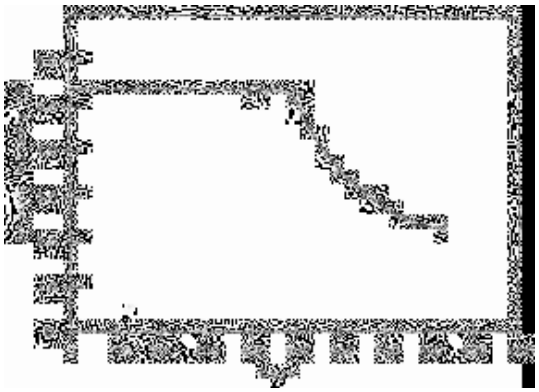

Figure 4. Stability of unstabilized PP at room temperature. Significant molecular weight loss occurs at 500 days. Reproduced from Oswald and Turi 1965.

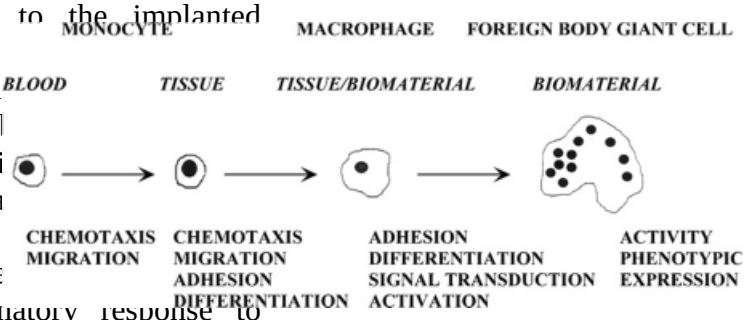

Figure 5. *In vivo* transition from blood-borne monocyte to biomaterial adherent monocyte/macrophage to foreign body giant cell at the tissue/biomaterial interface. There is ongoing research to elucidate the biological mechanisms that are considered to play important roles in the transition to foreign body giant cell development. From Anderson et al. Seminars in Immunology 2008.

Three key studies published characterize the host inflammatory response to implanted PP provide further evidence that PP mesh undergoes oxidative degradation *in vivo*. Gynemesh PS and UltraPro, which are Prolene meshes used in Ethicon's POP products, were implanted in rhesus macaques by sacrocolpopexy

[20] Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206; VV Iakovlev, ET Carey, J Steege. Pathology of Explanted Transvaginal Meshes. Int. J. Medical, Health, Pharmaceutical and Biomedical Eng. 8(9):510-513, 2014

[21] Tensile strength and host reponse towards different PP implant materials used for augmentation of fascial repair in a rat model. Deprest et al. Int Urogynecol J 18:619-26, 2007.

[22] Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias. U. Klinge,1,3 B. Klosterhalfen,2,3 M. Mu¨ller1 and V. Schumpelick1. Eur J Surg 1999; 165: 665–673

[23] C.R. Costello, S.L. Bachman, B.J. Ramshaw, S.A. Grant, Materials Characteriza- tion of Explanted Polypropylene Hernia Meshes, J. Biomed. Mater Res. Part B Appl. Biomat 83 (2007) 44e49; and C.R. Costello, S.L. Bachman, S.A. Grant, D.S. Cleveland, T.S. Loy, B.J. Ramshaw, Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient, Surg. Innov. 14 (2007) 168e176

after an abdominal hysterectomy.[24] After 12 weeks implantation time, the vagina-mesh tissue complexes were harvested and processed for histological and immunohistochemical analysis. Explanted Gynemesh PS and UltraPro meshes showed evidence of a foreign body reaction characterized by a dense mononuclear cell infiltrate near the surface of the mesh fibers. Mononuclear cells staining positive for the pan-macrophage marker CD68 were the cell type present at the highest density adjacent to the mesh fibers. The inflammatory response to all implanted PP meshes was characterized primarily by activated, pro-inflammatory M1 macrophages (Figure 7, Top Left).[25] The ratio of regenerative M2 macrophages to M1 macrophages was higher for the lower density UltraPro mesh compared to the higher density Gynemesh PS. This finding is consistent with the mesh burden concept that the magnitude of the foreign body reaction increases with the amount of mesh in contact with host tissue. Thus, the work by Moalli et al. establishes that the foreign body reaction to implanted PP mesh is dominated by pro-inflammatory M1 macrophages. In a study I co-authored with Dr. Vladimir Iakovlev in 2015, we examined 164 explanted PP pelvic meshes by microscopy.[26] Examination of histological sections revealed the presence of inflammatory cells near the surface of PP fibers, and staining for the oxidative enzyme myeloperoxidase expressed by adherent inflammatory cells was positive on the surface of the degraded layer of the PP fibers (Figure 7, Bottom Left). Another study published in 2015 confirmed that the foreign body reaction to implanted PP mesh results in oxidative degradation of the mesh.[27] PP pelvic meshes explanted from 11 patients were characterized by FTIR, GPC, SEM with energy-dispersive x-ray spectroscopy (EDS), TEM, and TGA and compared to meshes that had not been implanted. FTIR spectra of explanted PP mesh showed broad peaks centered at 3400 cm^{-1}, which correspond to hydroxyl and peroxide groups, and at 1700 – 1750 cm^{-1}, which correspond to carbonyl groups associated with ketones, aldehydes, and carboxylic acids. Importantly, this study demonstrated that oxidized PP, which does not contain nitrogen, and biological material, which does contain nitrogen, could be distinguished by a combination of EDS and SEM. Regions of PP fibers with transverse cracks that were free of biological material were found to contain oxidized PP (Figure 7 Right). Furthermore, clean PP fibers that showed no evidence of transverse cracking revealed evidence of PP oxidation.

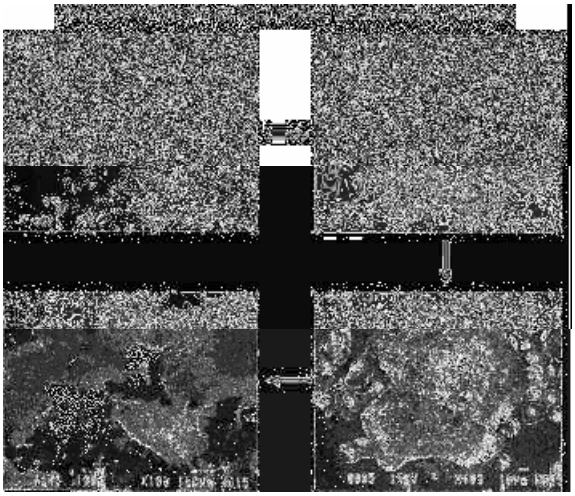

Figure 6. Scanning electron microscopy images of an Elasthane 80A Polyurethane surface from an in vivo cage study showing the morphological progression of the foreign body reaction. The sequence of events at the Polyurethane surface includes (A) monocyte adhesion (0 days), (B) monocyte-to-macrophage development (3 days), (C) ongoing macrophage-macrophage fusion (7 days), and (D) foreign body giant cells (14 days).. From JM Anderson et al., Foreign body reaction to biomaterials. Seminars in Immunology 20:86-100, 2008.

[24] Moalli et al., Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque. Am J Obstet Gynecol. 2015 Nov;213(5):668.e1-668.e10;
[25] JM Anderson et al., Foreign body reaction to biomaterials. Seminars in Immunology 20:86-100, 2008
[26] VV Iakovlev, SA Guelcher, R Bendavid. *In vivo* degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *Journal of Applied Biomedical Materials Research B: Applied Biomaterials*, 2015 Aug 28 doi: 10.1002/jbm.b.33502
[27] A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. In vivo oxidative degradation of polypropylene pelvic mesh. Biomaterials 73:131-141, 2015.

Taken together, these findings are consistent with the early observations of Liebert et al. and the scientific principles of the foreign body reaction. Implanted PP mesh is infiltrated by inflammatory cells, which are predominantly M1 pro-inflammatory macrophages. Macrophages in close proximity to the PP fiber surface secrete ROS, resulting in oxidation of the PP fibers. Consequently, the foreign body response to PP is elevated when more PP is present. As noted below, this principle has been acknowledged by Ethicon employees and consultants, who have noted that heavy-weight meshes like the Gynemesh and TVT induce a greater foreign body reaction than light-weight meshes.

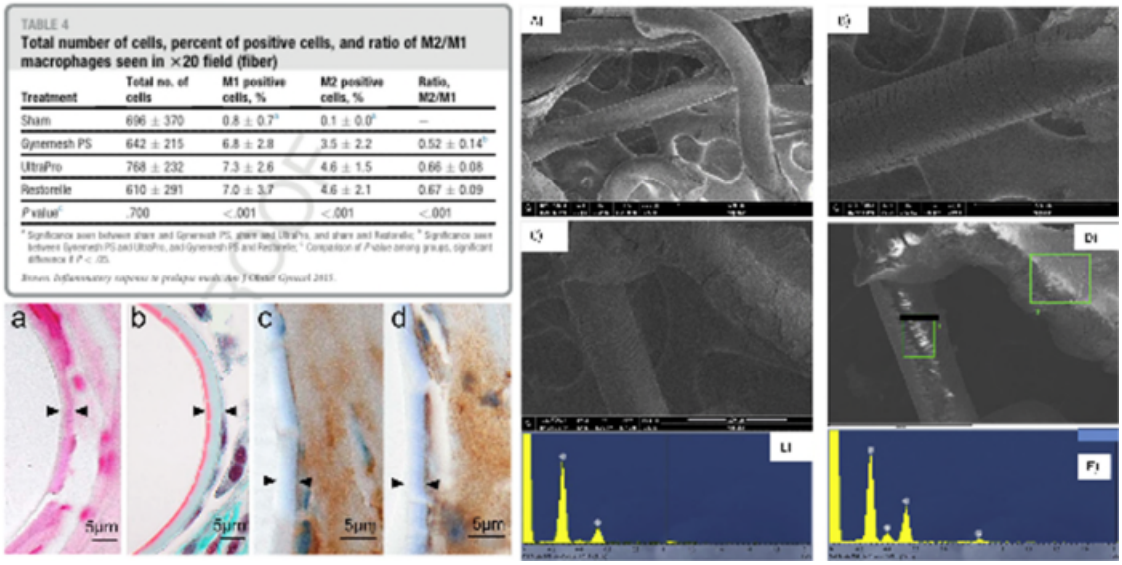

TABLE 4
Total number of cells, percent of positive cells, and ratio of M2/M1 macrophages seen in ×20 field (fiber)

Treatment	Total no. of cells	M1 positive cells, %	M2 positive cells, %	Ratio, M2/M1
Sham	696 ± 370	0.8 ± 0.7*	0.1 ± 0.0*	–
Gynemesh PS	642 ± 215	6.8 ± 2.8	3.5 ± 2.2	0.52 ± 0.14*
UltraPro	768 ± 232	7.3 ± 2.6	4.6 ± 1.5	0.66 ± 0.08
Restorelle	610 ± 291	7.0 ± 3.7	4.6 ± 2.1	0.67 ± 0.09
P value†	.700	<.001	<.001	<.001

* Significance seen between sham and Gynemesh PS, graft and UltraPro, and sham and Restorelle. † Significance seen between Gynemesh PS and UltraPro, and Gynemesh PS and Restorelle. ‡ Comparison of *P* value among groups, significant difference if *P* < .05.

Brown. Inflammatory response to prolapse mesh after 3 years. Obstet Gynecol 2015.

Figure 7. Oxidative degradation of PP mesh *in vivo*. Top Left: Table listing the total number of cells, percent of positive cells, and ratio of M2/M1 macrophages seen in x20 field (fiber) (Moalli et al., Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque.) Bottom Left: Additional stains of PP mesh, all images taken with 100x oil immersion objective and cropped to a different magnification, polypropylene degrada-tion layer is pointed between arrowheads: (a) Von Kossa stain is negative for calcium in the brittle "bark" (would stain calcium black), (b) trichrome stain shows that the deeper parts of the "bark" have smaller staining porosity (red) than those close to the surface (green) which correlates with TEM findings [Figure 6(b)], (c) immunohistochemical stain for immunoglobulin G (IgG, stained brown). IgG is present in almost all human tissues and fluids. It is deposited on the surface of degraded polypropylene but is not mixed within it. (d) Immunostain for the oxidizing enzyme of inflammatory cells myeloperoxidase (stains brown). (VV Iakovlev. *In vivo* degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients.) Right: A) SEM of explanted Pinnacle Mesh fibers [XP-7]. B) SEM of explanted Pinnacle Mesh fibers [XP-7]. C) SEM of explanted Pinnacle Mesh fibers [XP-7]. D) SEM image with regions selected for EDS. E) EDS Spectra from region 1 in D. F) EDS Spectra from region 2 in D. (A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. In vivo oxidative degradation of polypropylene pelvic mesh, Biomaterials, 2015.).

3) The dynamic environment where the Prolene mesh is implanted coupled with the foreign body reaction leads to oxidation, chain scission, reduction in molecular weight, embrittlement, degradation, flaking, pitting, and cracking;

In an early study, Prolene sutures implanted for 1 – 2 years in a canine thoracoabdominal bypass model showed evidence of transverse cracks and peeling (Mary 1998).[28] Several more recent studies have reported degradation of explanted PP pelvic mesh. In the first study characterizing explanted pelvic mesh, Clavé et al. reported that 42% of the explants

[28] Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206

showed evidence of chronic inflammation, characterized by an infiltrate of mononuclear cells and FGBCs. SEM analysis revealed that the implants were degraded, and that degradation was observed in meshes that had been implanted for at least 3 months.[29]

In the study that I co-authored with Dr. Iakovlev[30], a layer of degraded PP was observed by optimal microscopy near the surface of the fibers in the explanted mesh (Figure 7). Micro-cracks were present in the degraded PP layer. Degradation and cracking of the polypropylene fibers was observed as early as 18 months for a cohort of 23 explanted PP SUI devices.

Mays et al. also observed degradation of fiber in explanted PP mesh using SEM. Using a combination of SEM and EDS, the authors were able to distinguish between fibers that were clean and those that were coated with biological material. Explanted fibers were observed that showed evidence of severe transverse cracks (Figure 7), which was accompanied by oxidative degradation of the fibers. The authors identified the mechanism of PP degradation as comprising the following steps: infiltration of inflammatory cells that secrete ROS in close proximity to the PP mesh fibers, oxidative degradation of the PP fibers characterized by the appearance of hydroxyl and carbonyl groups in the FTIR spectra, a reduction in molecular weight, embrittlement, cracking, and fragmentation of the PP fibers.

4) PP mesh is known to fray under tension and release particles while being handled and implanted. The human body does not stop responding to these particles or to the PP mesh unless the product is removed in its entirety

As an example of how oxidation of an implanted biomaterial affects its performance, poly(ether urethane)s (PEUs) were used as pacemaker lead insulation due to their improved mechanical properties as compared to silicone rubber. While PEU elastomers were believed to be biocompatible for many years, they are now known to undergo environmental stress cracking due to oxidative degradation of the polyether component and subsequent loss in molecular weight.[31] Adherent macrophages and FBCGs were shown to be responsible for environmental stress cracking. Thus oxidative degradation and environmental stress cracking comprise a vicious cycle in which oxidative degradation drives the embrittlement of the polymer surface and its subsequent cracking, which in turn exposes new surfaces of the material to oxidative degradation. Another study has shown that ROS actively degrades lysine-derived poly(ester urethane)s *in vivo* by an oxidative mechanism.[32] Thus, oxidative degradation of biomaterials *in vivo* in response to ROS secreted by inflammatory cells is well known.

Since the foreign body reaction is present at the biomaterial surface for the lifetime of the

[29] Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J (2010) 21:261-270

[30] VV Iakovlev, SA Guelcher, R Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. Journal of Applied Biomedical Materials Research B: Applied Biomaterials, 2015 Aug 28 doi: 10.1002/jbm.b.33502

[31] *Id.*

[32] AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. Biomaterials 32(2):419-29, 2011. See also Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. Biomaterials 35(12):3766-76, 2014.

implant, the oxidative process is ongoing as long as the implant is present.[33] Considering the ongoing foreign body reaction as well as the known susceptibility of PP to oxidation, the mechanical and physical properties of Ethicon's PP mesh will change after it is implanted.

In addition, the properties of Ethicon's PP mesh have been shown to change under tension and while the mesh is being handled.[34] The medical literature and Ethicon's internal studies have reported that particles are lost or shed from the TVT mesh while it is in the box and while it is being implanted.[35] The foreign body reaction to shed particles will be similar to that for the TVT mesh. The body will not stop responding to any particles that are shed inside the body during implantation until those particles are removed in their entirety.

5) **Ethicon's pelvic meshes are intended to last for the lifetime of the patient, but the presence of antioxidants does not permanently protect the PP against degradation, and thus it is not possible to guarantee that these meshes will perform their intended function after implantation.**

Although PP can never be considered inert, it is stabilized against oxidation by adding antioxidants to the molten polymer, which are intended to act as scavengers that will react with oxidative species.[36] The enduring nature of the foreign body reaction emphasizes the need for antioxidants to be added to biomaterials such that the time to oxidation, degradation, and embrittlement is extended.[37] PP in its pure (i.e., unstabilized) form degrades rapidly *in vivo*, with an induction period of only 108 days[38], and carbonyl groups were detected in unstabilized PP by infrared spectroscopy within 50 – 90 days.[39] Liebert et al. also tested stabilized PP in the hamster subcutaneous implant model. Oxidation of stabilized PP was observed, but the experiment ended at 100 days, at which time induction had not been observed for stabilized PP filaments. Consequently, the eventual *in vivo* induction time for stabilized PP has not been reported.

Stabilization with antioxidants is not permanent, since the purpose of using antioxidants is to react with any oxidative species (such as ROS) to prevent their reaction with PP.[40] These stabilizers are distributed throughout the PP, however, and can only protect the polymer if they are in the proper location and only until they are exhausted. The antioxidant package must be optimized for the intended use to achieve maximum service life of the polymer. Neither the Santonox R nor the dilauralthiodipropionate (DLTDP) antioxidant in the Prolene resin used to manufacture Prolene mesh [41] is designed to protect against the ROS secreted by inflammatory cells *in vivo.* Santonox R is a hindered phenolic antioxidant

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[33] Foreign Body Reaction to Biomaterials. James M. Anderson, Analiz Rodriguez, and David T. Chang. Semin Immunol. 2008 April ; 20(2): 86–100.
[34] ETH.MESH.01813975; ETH.MESH.01317515; ETH.MESH.03905472; ETH.MESH.00541379; ETH.MESH.00863391.
[35] *Id.*
[36] E. Rene de la Rie. Polymer Stabilizers. A Survey with Reference to Possible Applications in the Conservation Field. Studies in Conservation 33(1988) 9-22
[37] James M. Anderson, Analiz Rodriguez, and David T. Chang. Foreign Body Reaction to Biomaterials. Semin Immunol. 2008 April ; 20(2): 86–100.
[38] Liebert et al. Subcutaneous implants of PP filaments. JBMR 10:939-51, 1976.
[39] *Id.*
[40] *Id.*
[41] Eth.Mesh.02268620

designed to protect Prolene during high-temperature processing (compounding and extrusion), while DLTDP is designed to protect Prolene from oxidation during long-term storage. Because *in vivo* oxidation and degradation are ongoing in response to the foreign body reaction, the antioxidant will eventually be depleted, resulting in oxidation and degradation of the PP mesh and changes to its properties over time. This cycle of depletion of antioxidants through reaction with ROS followed by the eventual degradation of the surface of the mesh will not stop until all of the mesh is removed, since cracking exposes new surfaces to ROS and the reaction begins anew.[42]

6) The effects of oxidation on the stability of Prolene were known to Ethicon prior to launching its SUI and POP devices, but the company did not consider the risks associated with polypropylene oxidation on the stability of Prolene mesh, to the detriment of patients implanted with the devices.

Ethicon first reported evidence of Prolene oxidation and degradation in internal documents from the 1980s. These documents report evidence of chronic inflammation, oxidation, and degradation (micro-cracking) of Prolene sutures similar to that published in the scientific literature described above. Several relevant studies are reviewed in greater detail below.

In 1981, the depth of surface cracks was measured for explanted cardiovascular and ophthalmic Prolene sutures.[43] The crack depth varied from 0.5 – 4.5 microns. Another memo in 1983 reported cracking of explanted Prolene sutures.[44] One of the explanted sutures showed only 54% of its original strength. The memo noted that the histological evaluation of explanted sutures was consistent with previous studies, characterized by a foreign body reaction and a "degraded acellular infiltrate." This document also refers to a Prolene Microcrack Committee. Thus, Ethicon was sufficiently aware of Prolene surface cracking to form a committee to investigate the mechanism of cracking.

Two memos written in 1984 investigated the cause of microcracking of explanted PP sutures from both ophthalmic and cardiovascular applications[45]. Sutures that were in the body for more than two years exhibited surface or severe transverse cracks. The thickness of the crack layer ranged from 2 – 5 microns thick. Dr. Peter Moy recognized in a November 5, 1984 report that "oxidative degradation is another mechanism through which transverse cracks may be produced on oriented fibers."[46] In an attempt to reproduce the observed cracking *in vitro*, Prolene sutures were incubated in aqueous 30% hydrogen peroxide for up to 1 year. Despite the fact that transverse cracks were not observed, infrared spectroscopy revealed evidence of oxidation products, which prompted Dr. Moy to note that "the possibility of a highly specific *in vivo* oxidation process remains." These findings are consistent with the foreign body reaction, which produces ROS stronger than hydrogen peroxide[47]. If treatment with 30% hydrogen peroxide caused oxidation of the PP suture (as reported by Dr. Moy), then ROS secreted by adherent macrophages would also be expected to cause oxidation. Dr. Moy also cited thermal stability and electron microdiffraction data supporting his hypothesis that at least a portion of the cracked layer contained protein. He recommended that an additional study was necessary to test this

[42] James M. Anderson1,2,*, Analiz Rodriguez1,*, and David T. Chang2. Foreign Body Reaction to Biomaterials. Semin Immunol. 2008 April ; 20(2): 86–100.
[43] Eth.Mesh.12831405.
[44] Eth.Mesh.15955438-15955473.
[45] ETH.MESH.15958452, ETH.MESH.15406978, ETH.MESH.15958470
[46] ETH.MESH.1595843
[47] Zhao AH, McNally AK, et al.Human plasma ð2-macroglobulin promotes in vitro oxidative stress cracking of Pellethane 2363-80A: In vivo and in vitro correlations. J Biomed Mater Res (1993) 27: 379-389

hypothesis by performing TEM analysis of known oxidized Prolene samples. Another memo dated November 13, 1984, reported that Prolene microcracks were evaluated by Attenuated Total Reflectance (ATR) and FTIR.[48] These studies found that the cracked Prolene surface is a composite of oxidized polypropylene and adsorbed protein. Surface protein was removed with Soluene treatment, but adsorbed protein remained in the microcracks. Thus, the November 13, 1984 memo by Dan Burkley concludes that the cracked layer contained both oxidized Prolene as well as protein.

In 1985, a series of experiments was proposed, including microscopic FTIR, TEM, and histology, to determine the clinical functionality of cracked sutures, the cracking mechanism, and effects of antioxidant concentration.[49] Dr. Moy further noted that laboratory experiments had not yet replicated the cracking observed in explants, and proposed a systematic evaluation of explanted Prolene sutures.

In 1987, Professor Guidoin provided Ethicon with his explanted sutures, which had been cleaned using a bleach solution as explained in Mr. Burkley's laboratory notebook.[50] SEM images of sutures explanted after 8 years revealed evidence of severe cracking. Another cohort of explanted sutures was scraped with a needle and the scrapings tested by calorimetry and FTIR. The waxy scrapings showed a melting point of 147 – 156^{o}C, which is comparable to that of degraded Prolene. Non-degraded Prolene melts over the range 155 – 165^{o}C. Scrapings were also melted on a KBr window to obtain FTIR spectra, which showed peaks associated with β-keto esters known to be formed during PP oxidation. Mr. Burkley noted in his notebook and memo that "no protein species or peptide bonds were suggested." A memo reporting on a follow-up meeting confirmed the findings that no protein was found on the surface and that Prolene degradation occurred on the surface of the fibers.[51] Several follow-up studies were proposed, including investigating the relationship between antioxidant concentration and polypropylene degradation and cracking. However, to my knowledge these studies were not performed.

In 1991, a 91-day rat subcutaneous implantation study was performed to assess the tissue reaction for several PP-based surgical meshes, including the Prolene mesh used in the SUI and POP devices.[52] All meshes, including Prolene and Prolene Soft, showed evidence of chronic inflammation at 7 and 91 days. Drs. Barbolt and Hutchinson concluded that all meshes showed evidence of a mild inflammatory reaction and infiltration of connective tissue. Furthermore, images of histological sections revealed evidence of adherent macrophages on the surface of the Prolene fibers.

As noted above, Ethicon researchers sought to replicate the surface cracking of Prolene sutures in an *in vitro* experiment. In the 1990s, the effects of the foreign body reaction on biomedical implants were first elucidated. All implantable medical devices are susceptible to the dynamic nature of the environment in which they are implanted. Environmental stress cracking of implanted biomaterials is controlled by three factors: (1) residual stress in the biomaterial, (2) a source of chemical degradation in the body, and (3) the chemical structure of the biomaterial.[53] Poly(ether urethane)s used as pacemaker lead insulation are an example of how oxidation of an implanted biomaterial can lead to Environmental Stress

[48] ETHMESH15958336
[49] ETHMESH15958445
[50] Eth.Mesh.00000367, Eth.Mesh.12831391
[51] Eth.Mesh.12831407
[52] Eth.Mesh. 02319001, eth.mesh.01425079
[53] Anderson et al. Cellular interactions with biomaterials: in vivo cracking of pre-stressed Pellethane 2363-80A. JBMR 24: 621-37, 1990.

Cracking (ESC) and device failure. While poly(ether urethane) elastomers were believed to be biocompatible for many years, they are now known to undergo ESC due to oxidative degradation of the polyether component and subsequent loss in molecular weight.[54] As shown in Figure 8, adherent macrophages and FBCGs were responsible for environmental stress cracking of poly(ether urethane)s *in vivo*.[55] A later study found that *in vivo* stress cracking of this poly(ether urethane) was reproduced *in vitro* by treating pre-stressed polymer specimens with an oxidative medium (10% hydrogen peroxide with 0.10 M cobalt chloride).[56] The cobalt chloride catalyzes the decomposition of the hydrogen peroxide to form hydroxyl radicals, a form of ROS that attacks the polymer. Under these conditions simulating the isolated microenvironment between the surface of the biomaterial and the cell, *in vitro* stress cracking was similar in appearance to that observed *in vivo*. Furthermore, infrared spectroscopy showed that ROS participated in the oxidative degradation process.[57] Thus, oxidative degradation and environmental stress cracking have a synergistic effect on the failure of poly(ether urethane) catheter lead insulation, by which oxidative degradation drives the embrittlement of the polymer surface and its subsequent cracking, which in turn exposes new surfaces of the material to oxidative degradation and ultimately clinical device failure.[58] Similar to poly(ether urethane)s, PP is susceptible to oxidation, which results in chain scission, loss of ductility (e.g., embrittlement),[59] and degradation, such as pitting, peeling, and cracking[60]. Embrittlement occurs at a very low conversion in the chain scission process, and surface embrittlement of the PP fibers leads to crack initiation. Mechanical stress on the fibers will in turn enhance stress cracking and expose new PP surface to the oxidative environment. I have published two papers in the scientific journal *Biomaterials*, one in 2011 and one in 2014, using the same 20% H_2O_2 /0.1 M cobalt chloride system to measure the oxidative degradation rate of poly(ester urethane) and poly(thioketal urethane) scaffolds. Thus, this *in vitro* oxidative degradation test is well established in the scientific literature, and was available to Ethicon at the time it developed the SUI and POP devices. Hov er done.

Ethicon has also been made aware of the an implantable medical device through the Mate ed that PP is incompatible with strong oxidizer is exposed to reactive oxygen species, which a gn body reaction.

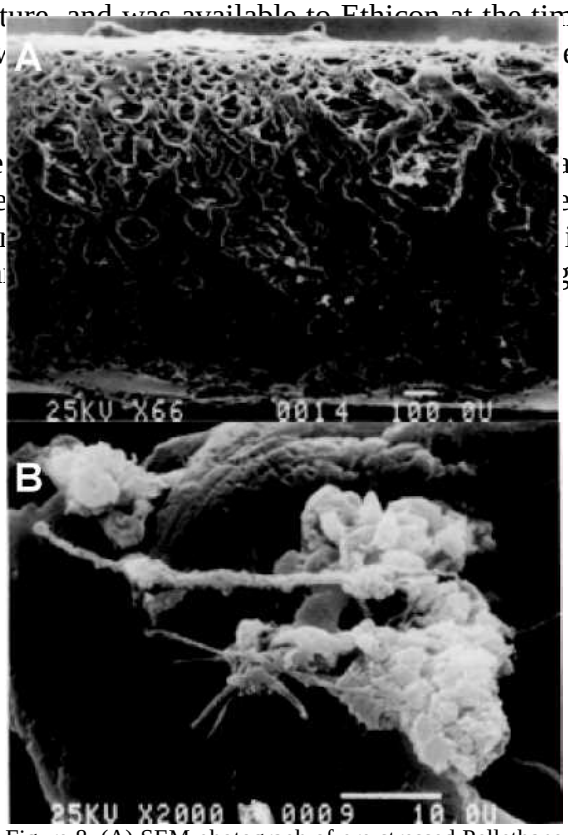

Figure 8. (A) SEM photograph of pre-stressed Pellethane 80A specimen implanted for 5 weeks. The specimen had severe cracking. Original magnification x66. (B) SEM photograph (at higher magnification) of pre-stressed Pellethane 80A specimen implanted for 5 weeks. Cellular adhesion was present. Original magnification x2000. From Zhao et al. JBMR 24:621, 1990.

[54] *Id*.
[55] Zhao et al. JBMR 24:621, 1990.
[56] Zhao et al. JBMR 27:379-89, 1993.
[57] Wiggins MJ, Wilkoff B, Anderson JM, Hiltner A. Biodegradation of polyether polyurethane inner insulation in bipolar pacemaker leads. J Biomed Mater Res 2001;58(3):302–7
[58] James M. Anderson1,2,*, Analiz Rodriguez1,*, and David T. Chang2. Foreign Body Reaction to Biomaterials. Semin Immunol. 2008 April ; 20(2): 86–100.
[59] Fayolle et al. Initial steps and embrittlement in the thermal oxidation of stabilized polypropylene films. Polym Degrad Stability 75:123-9, 2002
[60] VV Iakovlev, ET Carey, J Steege. Pathology of Explanted Transvaginal Meshes. Int. J. Medical, Health, Pharmaceutical and Biomedical Eng. 8(9):510-513, 2014
[61] ETH.MESH.05439518

The report from Mesh Repair of Uterovaginal Prolapse meeting in May 1997 noted that an ideal mesh would have lower density compared to that of the TVT to minimize the foreign body reaction.[62] Similar concerns were noted in a discussion document for the design of new mesh for prolapse repair, in which it was noted that the mesh used in the TVT is not the ideal material for anterior prolapse, and that the amount of foreign body should be minimized to reduce the risk of complications.[63]

The hernia literature also provides evidence that the foreign body reaction alters polypropylene *in vivo*. In a study evaluating non-degradable meshes explanted from 17 patients that had surgery for repair of abdominal wall defects, a foreign body reaction characterized by granulation tissue and inflammatory cells 3 – 24 months post-implantation was seen.[64] The PP meshes from this study showed more inflammatory cells and fibroblasts near the mesh interface when compared to PTFE and polyester.

Despite internal and published studies to the contrary, Ethicon documents further indicate that their sales force was instructed to "[r]eassure [surgeons] that PROLENE is proven to be inert and there are hundreds of papers going back 25 years to reinforce this point."[65] However, Daniel F. Burkley, a Principal Scientist at Ethicon, testified that in his 34 years at the company, he was only familiar with one study that was conducted regarding the changes that occurred due to oxidative degradation of explanted polypropylene suture or mesh.[66] Mr. Burkley also testified that this study showed that changes due to oxidation were still progressing after seven years of implantation.[67]

7) PP mesh is not inert and its properties change after implantation, which can lead to adverse events in an implantee; using heavy-weight mesh directly correlates to more PP being exposed to the foreign body reaction and greater changes after implantation, which increases the risk of complications.

The literature has confirmed that the properties of PP mesh change after implantation, causing adverse events like, pain, scarring and inflammation. In addition, Ethicon employees and consultants, both before and after the TVT was launched, have noted that heavy-weight meshes like the TVT comprise significantly more polypropylene than sutures or light-weight meshes, and therefore the foreign body reaction and resulting changes on the surface of the TVT device will be much greater than that for a lightweight mesh or a non-load bearing suture.[68] These findings are supported by the conclusions drawn by external consultants and Ethicon employees, as well as the available scientific literature reporting PP oxidation in response to cell-secreted ROS and complications associated with the mesh used in the TVT.[69]

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[62] Eth.Mesh.12006257
[63] Eth.Mesh.12009027
[64] Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias. U. Klinge,1,3 B. Klosterhalfen,2,3 M. Mu¨ller1 and V. Schumpelick1. Eur J Surg 1999; 165: 665–673
[65] ETH.MESH. 00865322
[66] Burkley Deposition 05/23/2013 P.312:23-313:24
[67] Burkely Deposition 05/23/2013 P.315:8-13
[68] Are Meshes With Lightweight Construction Strong Enough?; Jorge L. Holste*; ETHICON GmbH, R&D Europe, D-22841*, Norderstedt, Germany; J. Otto, E. Kaldenhoff, R. Kirschner-Hermanns, T. Muhl, U. Klinge. W.S. Cobb, K.W. Kercher, and B.T. Heniford.The Argument for Lightweight Polypropylene Mesh in Hernia Repair Surg Innov. Mar;12(1):63-9 (2005)
[69] Eth.Mesh.05479411, Eth.Mesh.07192929, Eth.Mesh.07192412.

More recently, Wood et al. published a comparison of three different explanted synthetic meshes (polypropylene, expanded polytetrafluoroethylene (ePTFE), and polyethylene terephthalate (PET)) from a single patient who had undergone three recurrent ventral hernia repairs.[70] Implantation times for the meshes were 3 years for the PP and PET meshes and 2 years for the ePTFE mesh. SEM images of explanted PP mesh "showed significant surface cracking" while the PET and ePTFE meshes did not. FTIR analysis also confirmed PP degradation from "free radical formation and oxidation of the polypropylene mesh while *in vivo."*

The Wood study supports the conclusions published by Clavé et al., which examined explanted pelvic meshes for degradation. Clavé reported that 42% of the explants showed evidence of chronic inflammation, characterized by an infiltrate of mononuclear cells and FGBCs. SEM analysis revealed that the implants were degraded, and that degradation was observed in meshes that had been implanted for at least 3 months.[71]

The findings of the Clavé study findings reinforced work done by Costello et al., who reported PP mesh oxidation and embrittlement as being a cause of mesh degradation and complications *in vivo*.[72] Costello derived his conclusions from comparisons made between pristine and explanted samples via molecular weight, SEM imaging, and compliance testing. Those authors reported that all three of these methods confirmed that PP mesh had degraded *in vivo*, most likely by oxidation.[73]

Another study investigated 14 explanted hernia mesh samples observed by SEM that 85% of the samples showed evidence of cracking, fissures, and peeling.[74] After host tissue was removed, the mesh samples remained folded and contracted, evidencing that mesh samples were permanently changed after implantation.

In a 2015 study I co-authored with Dr. Vladimir Iakovlev analyzing 164 explanted PP pelvic meshes, we reported the presence of adherent inflammatory cells expressing the oxidative enzyme myeloperoxidase, degradation of polypropylene, and micro-cracking near the surface of the polypropylene fibers. Degradation of explanted meshes was observed as early as 18 months.[75] Similar findings were reported by Mays et al., who observed oxidative degradation and transverse cracking of explanted PP pelvic mesh.[76]

Most importantly, these studies linked complaints of chronic pain and sclerosis to the foreign body reaction to implanted PP mesh and the consequent degradation and micro-

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[70] Wood, A.J., et al. *Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET hernia meshes from an Individual Patient*. J. MATER. SCI. MATER. MED. 24(4): 1113-1122 (2013).

[71] Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J (2010) 21:261-270

[72] Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. Surg Innov. 14:168–176 Costello CR, Bachman SL, Grant SA, Cleveland DS, Loy TS, Ramshaw BJ (2007); Materials characterization of explanted polypropylene hernia meshes. J Biomed Mater Costello CR, Bachman SL, Grant SA (2007) Res Part B: Appl Biomater 83B:44-49

[73] *Id*.

[74] Materials characterization of explanted polypropylene hernia meshes. J Biomed Mater. Res Part B: Appl Biomater 83B:44-49

[75] VV Iakovlev, SA Guelcher, R Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. Journal of Applied Biomedical Materials Research B: Applied Biomaterials, 2015 Aug 28 doi: 10.1002/jbm.b.33502

[76] A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. In vivo oxidative degradation of polypropylene pelvic mesh. Biomaterials 73:131-141, 2015.

cracking near the surface of PP fibers. These principles also apply to PP particles shed from the mesh during implantation, which is consistent with the testimony of Ethicon medical director Piet Hinoul that when particle loss occurs during implantation, the released particles result in inflammation that can cause pain.[77]

Large animal models, such as sheep, enable evaluation of PP mesh at longer time points and under conditions more representative of the clinical environment for SUI and POP repair.[78] A pilot study evaluated Prolene mesh implanted vaginally in sheep at 6 and 12 weeks.[79] The incidence of vaginal erosion was observed to be 33%. Macrophages and foreign body giant cells were also observed at 12 weeks. Two more recent studies have investigated differences between PP meshes implanted vaginally and abdominally using a sheep model.[80] PP mesh implanted vaginally showed more contraction and exposures, which are both mesh-related complications, than mesh implanted abdominally.[81] The authors further noted that the 15% incidence of vaginal exposures in all animals was comparable to that observed clinically, and found that mesh-related complications can be induced by vaginal mesh implantation. Contraction and folding, which have also been associated clinically with pain,[82] were also observed to be higher for vaginally implanted mesh compared to that implanted abdominally. In a follow-up study, the same authors investigated the effects of a collagen coating on mesh complications and made similar findings.[83] Vaginal exposures were observed in 33%, while no abdominal exposures were observed. Macrophages and foreign body giant cells were observed at 60 and 180 days in both vaginal and abdominal meshes. These findings led the authors to conclude that the sheep is an effective model to study complications of vaginal mesh. They further noted that the differential wound healing response and mechanical forces between the vaginal and abdominal wall environments may be responsible for the differences in mesh-related complications between the two implantation sites. Ethicon could have performed a similar sheep study at any time before or after the launch of its any of its mesh products to investigate the incidence of similar mesh-related complications. However, to my knowledge these studies have not been done.

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[77] Trial Testimony of Piet Hinoul, Batiste v. Ethicon, page 26-28

[78] Feola A, Endo M, Urbankova I, et al. Host reaction to vaginally inserted collagen containing polypropylene implants in sheep. Am J Obstet Gynecol 2015;212:474.e1-8.

[79] de Tayrac R1, Alves A, Thérin M.; Int Urogynecol J Pelvic Floor Dysfunct. 2007 May;18(5):513-20. Epub 2006 Aug 29.Collagen-coated vs noncoated low-weight polypropylene meshes in a sheep model for vaginal surgery. A pilot study.

[80] BJOG. 2013 Jan;120(2):244-50. doi:10.1111/1471-0528.12081. Graft-related complications and biaxial tensiometry following experimental vaginal implantation of flat mesh of variable dimensions. Manodoro S1, Endo M, Uvin P, Albersen M, Vláčil J, Engels A, Schmidt B, De Ridder D, Feola A, Deprest J. This study used Gynemesh M, which has polyglecaprone (not sure what this is) fibers that resorb; Am J Obstet Gynecol. 2015 Apr;212(4):474.e1-8. doi: 10.1016/j.ajog.2014.11.008. Epub 2014 Nov 8. Host reaction to vaginally inserted collagen containing polypropylene implants in sheep. Feola A, Endo M, Urbankova I, Vlacil J, Deprest T, Bettin S, Klosterhalfen B, Deprest J. This study used Bard meshes, one of which was coated with collagen.

[81] Deprest BJOG 2013

[82] Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, et al. An International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Neurourol Urodyn 2011;30:2–12.

[83] Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, et al. An International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Neurourol Urodyn 2011;30:2–12; Deprest AJOG 2015

Ethicon documents indicate that the company was aware of the Costello article in 2007, but never considered the effect of PP oxidation during these meshes design or product lifecycle. An Ethicon Medical Affairs employee, Tom Divilio, M.D., indicated that the Costello authors were "challenging our perception of polypropylene as an 'inert' material after implantation." He went on to note that "I think it's important that we understand what they are seeing as this group has a well-funded lab that will be looking at explanted mesh in great volume over the next couple of years and our current concepts are going to be challenged. Would appreciate it if we could think of some study designs that would confirm or refute their assumptions."[84] In 2012, Ethicon responded to a request by a British regulatory agency to explain how the 2010 publication by Clave et al impacts the performance of their products.[85] In this document, Ethicon noted "[we] are not aware of any findings that would impact the clinical performance of polypropylene monofilament"[86], and that "[p]olymers may be subject to surface degradation by these reactive species, the impact of which has not been clinically assessed."[87]

In summary, Ethicon scientists reported evidence of chronic inflammation, oxidation, and degradation (micro-cracking) of Prolene in preclinical studies and in human explants. These observations are consistent with the known susceptibility of polypropylene to oxidation outside the body, the known effects of the foreign body reaction on implanted biomaterials, and published studies on explanted PP mesh.[88] Despite the fact that Ethicon scientists recommended additional testing to confirm or exclude the oxidation mechanism, I have found no evidence that these tests (which were available to Ethicon during development of the SUI and POP devices) were performed. Consequently, the risks inherent to Prolene oxidation and degradation are detrimental to all of those who have been implanted with the SUI and POP devices.

[84] ETH.MESH. 05588123
[85] ETH.MESH. 07226481
[86] Id
[87] Id
[88] VV Iakovlev*, SA Guelcher, R Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *Journal of Applied Biomedical Materials Research B: Applied Biomaterials*, In Press

FACTS OR DATA CONSIDERED IN FORMING OPINIONS

The opinions and the bases for those opinions are set forth above. In addition to my knowledge, skill training and experience as an engineer, the following depositions of Ethicon employees and the exhibits thereto were supplied to me: Cliff Volpe, Piet Hinoul, David Robinson, Sunny Rah, Aaron Kirkemo, Sean O'Bryan, Scott Ciarrocca, Vincenza Zaddem, Elizabeth Vailhe, Christophe Vailhe, Joerg Holste, Boris Batke, Daniel Burkley, Thomas Barbolt, Brigitte Hellhammer, Juergen Trzewik, Martin Weisberg, Axel Arnaud, Dan Smith, Prof Thomas Muehl, Dr. Bernd Klosterhalfen, Kevin Ong, Whenxin Zheng, Daniel Sexton, and Jeffrey Brent.

I have also considered the following material identified in Exhibit B.

In addition, the following reports were supplied to me: Dr. Howard Jordi, Dr. Russell Dunn, Prof Thomas Muehl, Prof. Bernd Klosterhalfen, Thomas Barbolt, Dr. Wenxin Zheng, and B. Todd Heniford, M.D. The findings of these experts are consistent with my opinions.

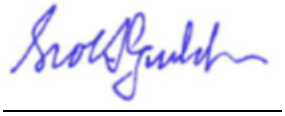
COMPENSATION

A fee sheet has been attached as Exhibit C.

LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FOUR YEARS

- IN RE PELVIC MESH AMS LITIGATION, SERRANO ET AL – SEPTEMBER 2013
- IN RE PELVIC MESH ETHICON LITIGATION, HUSKEY ET AL. - MARCH 2014
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, ALBRIGHT ET AL – JULY 2014
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, CARDENAS ET AL – AUGUST 2014
- IN RE PELVIC MESH ETHICON LITIGATION, HUSKEY ET AL – AUGUST 2014
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, BARBA ET AL - FEBRUARY 2014
- IN RE PELVIC MESH BARD LITIGATION, CORRIVEAU ET AL – NOVEMBER 2014
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, FRANKUM ET AL – DECEMBER 2014
- IN RE PELVIC MESH ETHICON LITIGATION, PERRY - DECEMBER 2014

- IN RE PELVIC MESH ETHICON LITIGATION, PERRY – JANUARY 2015
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, BARBA ET AL - MAY 2015
- IN RE PELVIC MESH AMS LITIGATION, KILGORE ET AL - FEBRUARY 2015
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, CARLSON – OCTOBER 2015



Scott Guelcher, Ph.D.
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1 Experience

PROFESSIONAL EXPERIENCE

Allied Chemical Company, Petersburg, VA **1989–1990**
Cooperative Education Student

Eastman Chemical Company, Kingsport, TN **1992–1995**
Chemical Engineer 1992–1994
Limited Service Employee (part-time) 1994–1995

Koninklijke Philips N.V., Eindhoven, The Netherlands **1998**
Trainee (Ph.D. Internship) 1998

Bayer Corporation, South Charleston, WV (formerly Lyondell) **1999–2003**
Associate Scientist, Polyurethanes Division 1999–2001
Senior Associate Scientist, Polyurethanes Division 2001–2003

Vanderbilt University, Nashville, TN **2005–present**
Assistant Professor of Chemical and Biomolecular Engineering 2005–2012
Assistant Professor of Biomedical Engineering (secondary) 2011–2012
Associate Professor of Chemical and Biomolecular Engineering 2012–present
Associate Professor of Biomedical Engineering (secondary) 2012–present

EDUCATION

B.S. Chemical Engineering **1987–1992**
Virginia Tech, Blacksburg, VA
Summa Cum Laude

M.S. Chemical Engineering **1994–1996**
University of Pittsburgh, Pittsburgh, PA
Adviser: Shiao-Hung Chiang
Thesis: A hydrodynamic model of a multi-stage loop-flow flotation column

Ph.D. Chemical Engineering **1996–1999**
Carnegie Mellon University, Pittsburgh, PA
Adviser: John L. Anderson
Thesis: Investigating the mechanism of aggregation of colloidal particles during elecrophoretic deposition

Post-doctoral Fellow **2003–2005**
Carnegie Mellon University, Pittsburgh, PA
Department of Biomedical Engineering
Advisers: Jeffrey O. Hollinger and Eric Beckman

AWARDS

Faculty

NSF CAREER Award: Bioactive Weight-Bearing Bone/Polymer Composites	2009–2015
VINSE High Impact Paper Award	2014
Chancellor's Faculty Fellow	2015 - 2017

Post-graduate

NIH Ruth L. Kirschstein NRSA Post-doctoral Fellow	2003–2005

Graduate

Dean's Fellow, University of Pittsburgh (M.S.)	1994–1995
U.S. EPA Science To Achieve Results (STAR) Fellow (M.S.)	1995–1996
NASA Graduate Student Researchers Program Fellow (Ph.D.)	1997–1999
Parfitt Award for Best Paper, Carnegie Mellon Chemical Engineering Symposium	1998

Undergraduate

Marshall Hahn Engineering Scholarship, Virginia Tech	1987–1988
Tennessee Eastman Scholar	1988–1992
Allied-Signal Scholarship, Unit Operations Laboratory at University College London	1991

2 Publications

[1]Equal contributions *Corresponding author [&]Invited paper ***Grad/postdoc*** *Undergrad*

BOOK

1. **SA Guelcher**, JO Hollinger, eds. *An Introduction to Biomaterials*. Boca Raton: CRC Press 2006.

BOOK CHAPTERS

1. PJ Sides, JL Anderson, H Kasumi, **SA Guelcher**, YE Solomentsev. Electrokinetic and Thermocapillary Driven Aggregation of Particles and Bubbles on Surfaces. In *Transport Processes in Bubbles, Particles, and Drops*. Daniel De Kee, ed. New York: Taylor and Francis, 2000.
2. AB Celil, **SA Guelcher**, JO Hollinger, MJ Miller. Tissue Engineering Applications – Bone. In *The Biomedical Engineering Handbook: Tissue Engineering and Artificial Organs, 3rd ed*. JD Bronzino, ed. Boca Raton, CRC Press 2006.
3. **SA Guelcher**. Polyurethanes. In *An Introduction to Biomaterials*, 161 – 183. SA Guelcher and JO Hollinger, eds. Boca Raton, CRC Press 2006.
4. **SA Guelcher** and JO Hollinger. Introduction. In *An Introduction to Biomaterials*, 1 – 2. SA Guelcher and JO Hollinger, eds. Boca Raton, CRC Press 2006.
5. **SA Guelcher**. Biocompatibility of Injectable Materials. In *Injectable Biomaterials: Science and Applications*. B Vernon, ed. Woodhead Publishing, 2011.
6. ***EM Prieto***, **SA Guelcher**. Tailoring properties of polymeric biomedical foams. In *Biomedical Foams*. P Netti, Ed. Woodhead Publishing, 2014.
7. **SA Guelcher**. Other Growth Factors and Delivery Mechanisms. In *Biomaterials of Bone Grafts - Bench-top to Clinical Applications*. T Guda and J Ong, eds. Taylor and Francis Group, 2015
8. ***AJ Harmata***, **SA Guelcher**. Effects of surface modification on polymeric biocomposites for orthopaedic applications. In *Nanocomposites for Musculoskeletal Tissue Regeneration*. H Liu, ed. Woodhead Publishing, 2016.
9. **SA Guelcher**. Advances in Polyurethane Biomaterials. Polyurethane Foams for Bone Regeneration. J Guan and S Cooper, Eds. Woodhead Publishing, 2015.

BOOK REVIEWS AND NEWS REPORTS

1. **SA Guelcher**. *Mechanics of Biomaterials: fundamental Principles for Implant Design* by Lisa A. Pruitt and Ayyana M. Chakravartula. Reviewed by SA Guelcher. Materials Today 5(16):198-199, 2013.
2. **SA Guelcher.** Winning the Race to the Surface: Local Delivery of Infection Control Agents from Biomedical Implants. SIG News: Drug Delivery SIG, Biomaterials Forum 36(1):14-15, 2014.
3. **SA Guelcher** and FK Kasper. 3D Printing in Dentistry and Oral and Maxillofacial Surgery. SIG News: Dental SIG, Biomaterials Forum 38(1):14-15, 2016.

ARTICLES IN REFEREED JOURNALS

Link to all citations in Google Scholar

https://scholar.google.com/citations?user=R9G88asAAAAJ&hl=en&cstart=80&pagesize=20

1. **SA Guelcher**, YE Solomentsev, PJ Sides*, JL Anderson. Thermocapillary phenomena and bubble coalescence during electrolytic gas evolution. *J Electrochem Soc* 145:1848-1855, 1998.
2. **SA Guelcher**, YE Solomentsev, JL Anderson*. Aggregation of pairs of particles on electrodes during electrophoretic deposition. Powder Technology 110:90-97, 2000.
3. H Kasumi, YE Solomentsev, **SA Guelcher**, JL Anderson, and PJ Sides*. Thermocapillary flow and aggregation of bubbles on a solid wall. *Journal of Colloid Interface Science* 232:111 – 120, 2000.
4. YE Solomentsev, **SA Guelcher**, MB Bevan, and JL Anderson*. Aggregation dynamics for two particles during electrophoretic deposition at steady fields. *Langmuir* 16:9208 – 9216, 2000.
5. J Kim, **SA Guelcher**, S Garoff, JL Anderson. Two-particle dynamics on an electrode in ac electric fields. *Advances in Colloid and Interface Science* 96:131 –142, 2002.
6. **SA Guelcher**, K Gallagher, JE Didier, DK Klinedinst, JS Doctor, AS Goldstein, GL Wilkes, EJ Beckman, JO Hollinger*. Synthesis of biocompatible polyurethanes from aliphatic diisocyanates and diurea diol chain extenders. *Acta Biomaterialia* 1:471 – 484, 2005.
7. **SA Guelcher**, V Patel, K Gallagher, S Connolly, JE Didier, JS Doctor, JO Hollinger*. Injectable polyurethane foam scaffolds for bone tissue engineering. *Tissue Engineering* 12:1247 – 1259, 2006.
8. KO Dulaney, TW Pechar, JO Hollinger, **SA Guelcher**, AS Goldstein*. Synthesis and characterization of segmented poly(esterurethane urea) (PEUUR) elastomers for bone tissue engineering. *Acta Biomaterialia* 3(4):475-484, 2007.
9. **SA Guelcher**, A Srinivasan, ***AE Hafeman***, KM Gallagher, JS Doctor, SB McBride, JO Hollinger*. Synthesis, in vitro degradation, and mechanical properties of two-component poly(ester urethane)urea scaffolds: effects of water and polyol composition. *Tissue Engineering* 13(9):2321-33, 2007.
10. **SA Guelcher**, A Srinivasan, ***J Dumas***, JE Didier, JS Doctor, SB McBride, and JO Hollinger*. Synthesis, mechanical properties, biocompatibility, and biodegradation of polyurethane networks from lysine polyisocyanates. *Biomaterials* 29:1762 – 1775, 2008.
11. **SA Guelcher***&. Biodegradable polyurethanes: synthesis and applications in regenerative medicine. *Tissue Engineering Part B* 14(1):3 – 17, 2008.
12. T Stylianopoulos, CA Bashur, AS Goldstein, **SA Guelcher**, and VH Barocas*. Computational predictions of the tensile properties of electrospun fiber meshes: effect of fiber diameter and fiber orientation. *Journal of the Mechanical Behavior of Biomedical Materials* 1(4):326-335, 2008.
13. ***AE Hafeman, B Li***, T Yoshii, *K Zienkiewicz*, JM Davidson, and **SA Guelcher***&. Injectable biodegradable polyurethane scaffolds with release of platelet-derived growth factor for tissue repair and regeneration. *Pharmaceutical Research* 25(10):2387-99, 2008. PMC3842433.
14. H Enderling, NR Alexander, E Clark, KM Branch, L Estrada, C Crooke, J Jourquin, N Lobdell, MH Zaman, **SA Guelcher**, ARA Anderson, and AM Weaver*. Dependence of invadopodia function on collagen fiber spacing and crosslinking: computational modeling and experimental evidence. *Biophysical Journal* 95(5):2203-18, 2008.

15. NR Alexander, KM Branch, IC Iwueke, **SA Guelcher**, and AM Weaver*. Extracellular matrix rigidity promotes invadopodia activity. *Current Biology* 18(17):1295-9, 2008.
16. CA Bashur, RD Shaffer, LA Dahlgren, **SA Guelcher**, and AS Goldstein*. Effect of fiber diameter and alignment of electrospun polyurethane meshes on mesenchymal progenitor cells. *Tissue Engineering Part A* 15(9):2435-45, 2009.
17. ***B Li***, JM Davidson, and **SA Guelcher***. The effect of the local delivery of platelet-derived growth factor (PDGF-BB) from reactive two-component polyurethane scaffolds on the healing in rat skin excisional wounds. *Biomaterials* 30:3486–3494, 2009. PMC2683181
18. ***Li B***, T Yoshii, ***AE Hafeman***, JS Nyman, JC Wenke, and **SA Guelcher***. The effects of rhBMP-2 released from biodegradable polyurethane/microsphere composite scaffolds on new bone formation in rat femora. *Biomaterials* 30:6768–6779, 2009.
19. ***AE Hafeman***, *KJ Zienkiewicz*, E Carney, B Litzner, CW Stratton, JC Wenke, and **SA Guelcher***. Local delivery of tobramycin from injectable biodegradable polyurethane scaffolds. *Journal of Biomaterials Science: Polymer Edition* 21:95-112, 2010.
20. ***JE Dumas***, T Davis, GE Holt, T Yoshii, DS Perrien, JS Nyman, TM Boyce, **SA Guelcher***. Synthesis, characterization, and remodeling of weight-bearing allograft bone/polyurethane composites in the rabbit. *Acta Biomaterialia* 6:2394 – 2406, 2010.
21. ***B Li***, K Brown, JC Wenke, **SA Guelcher***. Sustained release of vancomycin from polyurethane scaffolds inhibits infection of bone wounds in a rat femoral segmental defect model. *Journal of Controlled Release* 145:221 – 230, 2010.
22. T Yoshii, ***AE Hafeman***, JS Nyman, JM Esparza, K Shinomiya, DM Spengler, GR Mundy, GE Gutierrez, **SA Guelcher***. A sustained release of lovastatin from biodegradable, elastomeric polyurethane scaffolds for enhanced bone regeneration. *Tissue Engineering Part A* 16(7):2369-79, 2010.
23. ***JE Dumas***, *K Zienkiewicz*, ***SA Tanner***, ***EM Prieto***, S Bhattacharyya, **SA Guelcher*.** Synthesis and characterization of an injectable allograft bone/polymer composite bone void filler with tunable mechanical properties. *Tissue Engineering Part A* 16(8):2505-18, 2010.
24. ***NS Ruppender***, AR Merkel, TJ Martin, GR Mundy, JA Sterling, **SA Guelcher***. Matrix rigidity induces osteolytic gene expression of metastatic breast cancer cells. *PLoS One* 5(11):e15451, 2010.
25. **SA Guelcher***. Sustained Release and Dual Delivery Strategies for Platelet-derived Growth Factor. A*dvances in Wound Care* 2:143-148, 2011.
26. ***AE Hafeman***, *KJ Zienkiewicz*, AL Zachman, HJ Sung, LB Nanney, JM Davidson, **SA Guelcher***. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. *Biomaterials* 32(2):419-29, 2011. PMC2997347.
27. A Parekh, ***NS Ruppender***, KM Branch, MK Sewell-Loftin, J Lin, *PD Boyer*, JE Candiello, WD Merryman, **SA Guelcher**, AM Weaver*. Sensing and modulation of invadopodia across a wide range of rigidities. *Biophysical Journal* 100(3):573-82, 2011.
28. McMahon, B.S., X. Qu, A.C. Jimenez-Vergara, C.A. Bashur, **S.A. Guelcher**, A.S. Goldstein, M.S. Hahn*. Hydrogel-electrospun mesh composites for coronary artery bypass grafts. *Tissue Engineering Part C Methods* 17(4):451-561, 2011.
29. K Brown, ***B Li***, T Guda, DS Perrien, **SA Guelcher**, JC Wenke*. Improving bone formation in a rat femur segmental defect by controlling BMP-2 release. *Tissue Engineering Part A* 17(13-14): 1735-1746, 2011.
30. JA Sterling and **SA Guelcher***&. Bone structural components regulating sites of tumor metastasis. *Current Osteoporosis Reports* 9:89–95, 2011.
31. **Guelcher SA,** Brown KV, ***Li B***, Guda T, ***Lee BH***, and JC Wenke*&. Dual-purpose bone grafts improve healing and reduce infection. *Journal of Orthopaedic Trauma* 25(8):477-82, 2011.
32. JS Nyman, *P Masui*, CA Patil, X-H Bi, E O'Quinn, **SA Guelcher**, DP Nicollela, and A Mahadevan-Jansen*. Measuring differences in compositional properties of bone tissue by confocal Raman spectroscopy. *Calcified Tissue International* 2011 Aug;89(2):111-22.
33. **SA Guelcher**, JA Sterling*&. Contribution of bone tissue modulus to breast cancer metastasis to bone. *Cancer Microenvironment* 4(3):247-59, 2011.

34. JC Wenke and **SA Guelcher***&. Dual delivery of an antibiotic and a growth factor addresses both the microbiological and biological challenges of contaminated bone fractures. *Expert Opinion on Drug Delivery* 8(12):1-15, 2011.
35. S Samavedia, HC Olsen, **SA Guelcher**, AS Goldstein, and AW Whittington*. Fabrication of a model continuously graded co-electrospun mesh for regeneration of the ligament-bone interface. *Acta Biomaterialia* 7(12):4131-8, 2011.
36. T Yoshii, ***JE Dumas***, A Okawa, D Spengler, **SA Guelcher***. Synthesis, characterization of calcium phosphates/polyurethane composites for weight bearing implants. *Journal of Biomedical Materials Research Part B: Applied Biomaterials* 100(1):32-40, 2012.
37. ***EJ Adolph, AE Hafeman***, KL Zienkiewicz, JM Davidson, **SA Guelcher***. Injectable biodegradable polyurethane scaffolds for wound healing. J*ournal of Biomedical Materials Research Part A* 100A: 450–461, 2012. PMC3288361
38. CE Nelson, MK Gupta, ***EJ Adolph***, JM Shannon, **SA Guelcher**, CL Duvall*. Sustained Local Delivery of siRNA from an Injectable Tissue Scaffold. *Biomaterials* 33(4):1154-61, 2012. PMC3232066
39. ***BH Lee***, ***B Li***, and **SA Guelcher***. Gel microstructure regulates proliferation and differentiation of MC3T3-E1 cells encapsulated in alginate beads. *Acta Biomaterialia* 8:1693–1702, 2012. PMC3314144.
40. ***JE Dumas***, P Brown-Baer, ***EM Prieto***, T Guda, R Hale, JC Wenke, **SA Guelcher***&. Injectable reactive biocomposites for bone healing in critical-size rabbit calvarial defects. *Biomedical Materials* 7(2): 024112, 2012.
41. S Samavedi, **SA Guelcher**, AS Goldstein, AR Whittington*. Response of bone marrow stromal cells to graded co-electrospun scaffolds and its implications for engineering the ligament-bone interface. *Biomaterials* 33:7727-35, 2012.
42. ***JM Page***, ***EM Prieto***, ***JE Dumas***, ***KJ Zienkiewicz***, JC Wenke, P Brown-Baer, **SA Guelcher***. Reactivity and biocompatibility of injectable polyurethane/allograft bone biocomposites. *Acta Biomaterialia, 8:4405–4416,* 2012.
43. CE Nelson, MK Gupta, ***EJ Adolph***, **SA Guelcher,** CL Duvall*. siRNA delivery from an injectable scaffold for enhanced wound repair. *Advances in Wound Care* 2(3): 93-99, 2013. PMC3623593
44. A Zachman, ***JM Page***, AR Boone, G Prabhakar, **SA Guelcher**, H-J Sung*. Elucidation of adhesion-dependent spontaneous apoptosis in macrophages using phase separated PEG/polyurethane film. *Acta Biomaterialia* 9(2):4964-75, 2013. PMC3606556
45. AL Zachman, SW Crowder, O Ortiz, ***KJ Zienkiewicz***, CM Bronikowski, SS Yu, TD Giorgio, **SA Guelcher,** JB Kohn, H-J Sung*. Pro-angiogenic and anti-inflammatory regulation by functional peptides loaded in polymeric implants for soft tissue regeneration. *Tissue Engineering Part A* 19(3-4):437-47, 2013. PMC3542873
46. KD Kavlock, K Whang, **SA Guelcher**, AS Goldstein*. Degradable Segmented Polyurethane Elastomers for Bone Tissue Engineering: Effect of Polycaprolactone Content. *Journal of Biomaterials Science: Polymer Edition* 24(1):77-93, 2013.
47. CJ Sanchez Jr., ***EM Prieto***, CA Kruger, ***KJ Zienkiewicz***, DR Romano, CL Ward, KS Akers, **SA Guelcher**, JC Wenke*. Effects of Local Delivery of D-Amino Acids from Biofilm-Dispersive Scaffolds on Infection in Contaminated Rat Segmental Defects. *Biomaterials* 34(30):7533-43, 2013.
48. AM Weaver AM, ***JM Page***, **SA Guelcher**, Parekh A*. Synthetic and tissue-derived models for studying rigidity effects on invadopodia activity. *Methods in Molecular Biology* 1046:171-89, 2013.
49. ***JM Page***, ***AJ Harmata***, **SA Guelcher***. Design and development of reactive injectable and settable polymeric biomaterials. *Journal of Biomedical Materials Research Part A* 101(12):3630-3645, 2013.
50. ***JE Dumas***, ***EM Prieto***, ***KJ Zienkiewicz***, T Guda, JC Wenke, JM Bible, GE Holt, **SA Guelcher***. Remodeling of Settable Allograft Bone/Polymer Composites with Initial Bone-like Mechanical Properties in Rabbit Femora. *Tissue Engineering Part A* 20(1-2):115-29, 2014.
51. PS Thayer, AF Dimling, DS Plessl, MR Hahn, **SA Guelcher**, LA Dahlgren, AS Goldstein*. Cellularized Cylindrical Fiber/Hydrogel Composites for Ligament Tissue Engineering. *Biomacromolecules* 15(1):75-83, 2014.

52. CE Nelson, AJ Kim, A Hanna, ***EJ Adolph***, F Yu, MK Gupta, K Hocking, JM Davidson, **SA Guelcher**, CL Duvall*. Tunable Delivery of siRNA from a Biodegradable Scaffold to Promote Angiogenesis *in vivo*. *Advanced Materials* 26(4):607-14, 2014.
53. ***EM Prieto***, ***JM Page***, ***AJ Harmata***, **SA Guelcher***&. Injectable Foams for Regenerative Medicine. *WIRE Nanomedicine and Nanobiotechnology* 6(2):136-54, 2014.
54. JL Martin, MK Gupta, ***JM Page***, F Yu, JM Davidson, **SA Guelcher**, CL Duvall*. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. *Biomaterials* 35(12):3766-76, 2014.
55. JA Sterling, **SA Guelcher***&. Biomaterial scaffolds for treating osteoporotic bone. *Current Osteoporosis Reports* 12(1): 48–54, 2014.
56. T Yoshii, ***AE Hafeman***, GE Gutierrez, GR Mundy, **SA Guelcher***. Local injection of lovastatin in biodegradable polyurethane scaffolds enhances bone regeneration. *Journal of Tissue Engineering and Regenerative Medicine* 8(8): 589–595, 2014.
57. ***AJ Harmata***, CL Ward, ***KJ Zienkiewicz***, JC Wenke, **SA Guelcher***&. Investigating the Effects of Surface-Initiated Polymerization of ε-Caprolactone to Bioactive Glass Particles on the Mechanical Properties of Settable Polymer/Ceramic Composites. *Journal of Materials Research* 29: 20, 2014.
58. AL Zachman, X Wang, J Tucker-Schwartz, S Fitzpatrick, SH Lee, **SA Guelcher**, M Skala, H-J Sung*. Uncoupling Angiogenesis and Inflammation in Peripheral Artery Disease with Therapeutic Peptide-loaded Microgels. *Biomaterials* 35(36): 9635-48, 2014.
59. ***EJ Adolph***, CE Nelson, TA Werfel, ***R Guo***, JM Davidson, **SA Guelcher***, CL Duvall&. Enhanced Performance of Plasmid DNA Polyplexes Stabilized by a Combination of Core Hydrophobicity and Surface PEGylation. *Journal of Materials Chemistry B*, 2(46), 8154 - 8164, 2014.
60. ***EJ Adolph***, JM Davidson, **SA Guelcher,** LB Nanney*. Biodegradable polyurethane scaffolds promote healing in a porcine full-thickness excisional wound model. *Journal of Biomaterials Science: Polymer Edition* 25: 1973-85, 2014.
61. B Lee, X Zhou, K Riching, KW Eliceiri, PJ Keely, **SA Guelcher**, AM Weaver, Y Jiang. A three-dimensional computational model of collagen network mechanics. *PLoS One* 9(11):e111896, 2014. PMC4227658
62. RW Johnson, AR Merkel, ***JM Page***, ***NS Ruppender***, **SA Guelcher,** JA Sterling*. Wnt signaling induces gene expression of factors associated with bone destruction in lung and breast cancer. *Clinical and Experimental Metastasis* 31(8):945-59, 2014.
63. ***R Guo***, CL Ward, JM Davidson, CL Duvall, JC Wenke, **SA Guelcher***. A Transient Cell-Shielding Method for Viable MSC Delivery within Hydrophobic Scaffolds Polymerized In Situ. *Biomaterials* 54:21-33, 2015.
64. ***JM Page***, AR Merkel, ***NS Ruppender,*** UC Dadwal, S Cannonier, ***R Guo***, S Basu, **SA Guelcher,** JA Sterling*. Matrix rigidity regulates the transition of tumor cells to a bone-destructive phenotype through integrin beta3 and TGF-beta receptor type II. *Biomaterials* 64:33-44, 2015.
65. ***JM Page***, AR Merkel, ***NS Ruppender,*** UC Dadwal, S Cannonier, ***R Guo***, S Basu, **SA Guelcher,** JA Sterling*. Altering adsorbed proteins or cellular gene expression in bone-metastatic cancer cells affects PTHrP and Gli2 without altering cell growth. *Data Brief* 4:440-6, 2015. PMC4534584
66. RD Cardwell, JA Kluge, PS Thayer, **SA Guelcher**, LA Dahlgren, DL Kaplan, AS Goldstein. Static and cyclic mechanical loading of mesenchymal stem cells on elastomeric, electrospun polyurethane meshes. *J Biomech Eng*. 137(7):071010, 2015.
67. ***AJ Harmata***, S Uppuganti, M Granke, **SA Guelcher**, JS Nyman*. Compressive fatigue and fracture toughness behavior of injectable, settable bone cements *Journal of the Mechanical Behavior of Biomedical Materials* 51:345-355, 2015.
68. ***R Guo***, ***S Lu, JM Page,*** AR Merkel, S Basu, JA Sterling, and **SA Guelcher***. Fabrication of 3D Scaffolds with Precisely Controlled Substrate Modulus and Pore Size by Templated-Fused Deposition Modeling to Direct Osteogenic Differentiation. *Advanced Healthcare Materials* 4(12): 1826-32, 2015.

69. ***R Guo***, A Merkel, JA Sterling, JM Davidson, **SA Guelcher***. Substrate Modulus of 3D-Printed Scaffolds Regulates the Regenerative Response in Subcutaneous Implants through the Macrophage Phenotype and Wnt Signaling. *Biomaterials* 73:85-95, 2015.
70. ***EM Prieto***, ***AD Talley***, S, Drapeau, K Kalpakci, **SA Guelcher***. Effects of particle size and demineralized bone matrix on remodeling of settable bone grafts in a rabbit femoral condyle defect model. *Journal of Biomedical Materials Research Part B: Applied Biomaterials* 103(8):1641-51, 2015.
71. ***AJ Harmata***, C Sanchez, JC Wenke, **SA Guelcher***. D-amino acid inhibits biofilm but not new bone formation in an ovine model. *Clinical Orthopedics and Related Research* 473(12):3951-61, 2015.
72. VV Iakovlev*, **SA Guelcher**, R Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *Journal of Biomedical Materials Research B: Applied Biomaterials* 2015 Aug 28. doi: 10.1002/jbm.b.33502. [Epub ahead of print].
73. ***EJ Adolph***, ***R Guo***, JM Davidson, **SA Guelcher**, LB Nanney*. Injectable, Settable Lysine-derived Polyurethane Scaffolds Delay Wound Contraction and Promote Healing of Full-Thickness Excisional Wounds in Pigs. *Journal of Biomedical Materials Research B: Applied Biomaterials* 2015 Sep 7. doi: 10.1002/jbm.b.33515. [Epub ahead of print].
74. ***AD Talley***, KN Kalpakci, KJ Zienkiewicz, DL Cochran, **SA Guelcher***. Effects of rhBMP-2 Dose and Ceramic Composition on New Bone Formation and Space Maintenance in a Canine Mandibular Ridge Saddle Defect Model. *Tissue Engineering Part A*, Tissue Eng Part A. 2016 Jan 22. [Epub ahead of print].

ARTICLES IN CONFERENCE PROCEEDINGS

1. **SA Guelcher**, A Srinivasan, JO Hollinger. Biodegradable poly(ester urethane)urea biomaterials for applications in combat casualty care. Proceedings of the 25th Army Science Conference, Orlando, FL, November 27-30, 2006.
2. ***AE Hafeman***, ***B Li***, JO Hollinger, and **SA Guelcher**. Release of BMP-2 and tobramycin from injectable, biodegradable polyurethane scaffolds for enhanced bone fracture healing. Proceedings of the 26th Army Science Conference, Orlando, FL, December 1 - 4, 2008.
3. *AC Brakefield*, ***EM Prieto***, **SA Guelcher**. A Characterization of Three Groups of MC3T3-E1 Pre-osteoblastic Cells to Aid in Testing of Polyurethane-Bone Scaffolds for Wound Healing. Young Scientist Journal May 2011.
4. *LK Moribe*, AJ Adolph, **SA Guelcher.** Optimizing transfection efficiency and determining release kinetics of plasmid DNA from polyurethane scaffolds in vitro. Young Scientist 2:11-13, 2012.
5. *J Davies*, ***EM Prieto***, and **SA Guelcher**. Characterization of Macrophage Behavior in the Human Immunoresponse and Bone Remodeling. Young Scientist 2013.
6. *M Lu*, ***EJ Adolph***, **SA Guelcher**. The Effect of Trehalose and Poly(lactic-co-glycolic acid) (PLGA) Microparticles on the Release Kinetics of Hydrophobic Drugs in Polyurethane Scaffolds. Young Scientist 2014.

3 Research Support

CURRENT AND COMPLETED EXTRAMURAL RESEARCH SUPPORT

Principal Investigator

1. EPA Science-to-Achieve-Results Graduate Fellowship (STAR) (Chiang) 09/01/1995 – 08/31/1996
   "A Hydrodynamic Model for a Multi-stage Loop-flow Flotation Column"
   Amount: $30,000/yr (up to 2 years)
   Source: EPA
   Investigators: SA Guelcher (Student), S-H Chiang (MS Thesis Advisor)
   Salary support: 100%

2. NASA Graduate Student Researchers Program (GSRP) 07/01/1997 – 08/01/1999
   "Investigating the Mechanism of Aggregation of Colloidal Particles during Electrophoretic Deposition"
   Amount: $24,000/yr (up to 3 years)
   Source: NASA
   Investigators: SA Guelcher (Student), JL Anderson (PhD Advisor)
   Salary support: 100%

3. NSF Small Business Innovative Research (SBIR) Phase I 07/01/2002 – 12/31/2002
   "Innovative Recovery of Natural Beta-Carotene from the Marine Alga Dunaliella salina"
   Amount: $100,000
   Investigators: JS Kanel (JS Kanel & Associates, PI), SA Guelcher (CoI)
   Salary support: 0%

4. Corporate Grant (Guelcher) 01/19/2006 – 03/01/2006
   "Resorbable Polyurethanes for Orthopedic Applications"
   Amount: $30,000
   Source: Osteotech, Inc.
   Investigators: SA Guelcher (PI)
   Salary support: 0%

5. W81XWH-06-1-0654USAMED (Guelcher) 08/01/2006 – 08/01/2007
   "Controlled delivery of BMP-2 with poly(ester urethane urea) scaffolds"
   Amount: $70,000
   Source: DOD/U.S. Army Institute for Surgical Research
   Investigators: SA Guelcher (PI)
   Salary support: 0%

6. W81XWH-07-1-0211 (Guelcher) 02/01/2007 – 01/31/2013
   "Orthopaedic Trauma Research Program. Improved healing of infected segmental bone defects through controlled delivery of FGF-2, PDGF, and tobramycin"
   Amount: $2,088,794
   Source: DOD/USAMRAA
   Investigators: SA Guelcher (PI), JC Wenke (Co-Investigator, USAISR)
   Salary support: 10%

7. DMR-0847711 (Guelcher) 07/01/2009 – 06/30/2014
   "CAREER: Bioactive Weight-Bearing Bone/Polymer Composites"
   Amount: $500,000
   Source: NSF/BMAT
   Investigator: SA Guelcher (PI)
   Salary support: 0%

5. DSR #20972 (Guelcher) 08/15/2009 – 08/14/2011
   "Development of an Injectable Bone Void Filler and Bioresorbable Bone Cement"
   Amount: $70,694
   Source: Osteotech, Inc. (now Metronic Sofamek Danor)
   Investigator: SA Guelcher (PI)
   Salary support: 2.8%

6. DMR-1006558 (Guelcher) 09/01/2010 – 08/31/2014

"A New Class of Biomaterials Programmed to Regulate Host Body Responses"
Amount: $168,426 to Guelcher lab ($272,520 total)
Source: NSF/DMR
Investigators: SA Guelcher (PI), HJ Sung (CoPI)
Salary support: 2.8%

7. R01 CA163499 (Guelcher) 09/01/2012 – 06/30/2017
"The Role of Mechanotransduction in Progression of Tumor-induced Bone Disease"
Amount: $726,875 to Guelcher lab ($1,548,965 total award)
Source: NIH/NCI
Investigators: SA Guelcher (Administrative Multi PI), JA Sterling (Multi PI)
Salary support: 8%

8. R01 AR3494768 (Guelcher) 04/15/2013 – 03/31/2017
"Injectable Weight-Bearing Bone Grafts for Healing of Tibial Plateau Fractures"
Amount: $1,066,452
Source: NIH/NIAMS
Investigators: SA Guelcher (Administrative Multi PI), JC Wenke (USAISR, Multi PI)
Salary support: 7%

9. VU-CIP 20972 (Guelcher) 06/26/2013 – 06/25/2014
"Development of an Injectable Bone Void Filler and Bioresorbable Bone Cement"
Amount: $74,346
Source: Kinetic Concepts, Inc.
Investigators: SA Guelcher (PI), Lillian Nanney (Co-Investigator), Jeff Davidson (Co-Investigator)
Salary support: 2%

10. VU-CIP 10228-13 (Guelcher) 04/02/2013 – 12/31/2014
"PEURegen e-Team"
Amount: $20,015
Source: NCIAA (now Venture Well)
Investigators: SA Guelcher (PI), AJ Harmata (Student investigator)
Salary support: 0%

11. VU-CIP 20972 (Guelcher) 04/02/2013 – 12/31/2014
"Development of an injectable bone void filler and bioresorbable bone cement"
Amount: $27,833
Source: Medtronic, Inc.
Investigators: SA Guelcher (PI)
Salary support: None

12. R01 AR064772 (Guelcher) 04/01/2014 – 03/31/2019
"Biofilm Dispersive Bone Grafts to Improve Healing of Contaminated Fractures"
Amount: $1,838,020
Source: NIH/NIAMS
Investigators: SA Guelcher (Administrative Multi PI), JC Wenke (Multi PI, USAISR), F Elefteriou (Co-I, VUMC)
Salary support: 10%

13. T32 DK101003 (Guelcher) 08/01/2014 – 07/31/2019
"Integrated Training in Engineering and Diabetes"
Amount: $2,353,538

Source: NIH/NIDDK
Role: PI
Salary support: 2%

Role other than Principal Investigator

14. W81XWH0420031 (Kohn, Rutgers University) 08/01/2005 – 07/01/2010
"A resorbable poly(ester urethane)/bone composite intramedullary rod for fracture fixation"
Amount: $312,859 to Guelcher lab from Rutgers
Source: DOD/USAMRAA-Center for Military Biomaterials Research (Subcontract from Rutgers University DOD-2110-PO5-694362)
Role: Project Leader (PI on Vanderbilt subcontract)
Salary support: 0%

15. R21 AR051945 (Goldstein, Va Tech) 08/10/2005 – 08/09/2007
"High-modulus Polyurethanes for Bone Tissue Engineering"
Amount: $124,641 to Guelcher lab from Va Tech ($342,345 total award)
Source: NIH/NIAMS
Role: Co-Investigator (PI on Vanderbilt subcontract)
Salary support: 0%

16. W81XWH0820034 (Kohn, Rutgers University) 03/15/2008 – 06/30/2014
"Reconstruction and Regeneration of the Craniofacial Complex"
Amount: $898,624 to Guelcher lab from Rutgers ($90,000,000 total award)
Source: DOD/Armed Forces Institute for Regenerative Medicine
Role: Project Leader (PI on Vanderbilt Subcontract)
Salary support: 4%

17. W81XWH0820034 (Kohn, Rutgers University) 03/15/2008 – 06/30/2014
"Expedited Commercialization of an Injectable Allograft Bone/Polymer Composite as a Treatment for Open Fractures"
Amount: $482,746 to Guelcher lab from Rutgers ($7,000,000 total award)
Source: DOD/Armed Forces Institute for Regenerative Medicine
Role: Project Leader (PI on Vanderbilt subcontract)
Salary support: 4%

18. P50 CA098131 (Arteaga, VUMC) 07/01/2008 – 06/30/2013
"SPORE in Breast Cancer"
Amount: $15,097 to Guelcher lab in Year 1 ($2,500,000 total Year 1) (participated for 1 year)
Source: NIH/NCI
Role: Co-investigator on bone project
Salary support: 0%

19. R01 AR056138 (Davidson, VUMC) 09/01/2009 – 06/30/2015
"Skin regeneration with stem cells and scaffolds"
Amount: $466,543 to Guelcher lab from VUMC
Source: NIH/NIAMS
Role: Multi PI
Salary support: 5%

20. VUMC Corporate Grant (Nanney, VUMC) 02/01/2011 – 01/31/2012
"Development of Bioresorbable Polyurethanes as Foam Dressings"

Source: Kinetic Concepts, Inc.
Amount: $75,000 to Guelcher lab ($149,104 total)
Role: Co-investigator
Salary support: 5.6%

21. U01 CA143059 (Weaver, VUMC) 03/01/2011 – 02/28/2016
"Multiscale Modeling of Tumor-ECM interactions in Breast Cancer"
Amount: $79,235 to Guelcher lab from VUMC ($2,451,394 total),
Source: NIH/NCI
Role: Co-investigator
Salary support: 3.3%

22. R21 EB012750 (Duvall, VUSE) 08/01/2011 – 06/30/2014
"Injectable Scaffold for Efficient, Tunable siRNA Delivery to Skin Wounds"
Amount: $15,000 to Guelcher lab from BME ($417,632 total)
Source: NIH/NIBIB
Role: Co-investigator
Salary support: 2.8%

23. W81XWH1420004 (Atala, Wake Forest Inst. of Regenerative Medicine) 01/01/2014 – 12/31/2019
"Injectable, Settable Bone Grafts for Reconstruction of Weight-bearing Craniofacial Bone Defects with Augmentation using Recombinant Human Growth Factors"
Amount: $839,188 to Guelcher lab from WFIRM ($75,000,000 total)
Source: DOD/Armed Forces Institute of Regenerative Medicine II
Role: Project Leader (PI on Vanderbilt Subcontract)
Salary support: 2.1%

24. BC141789P1 (Sterling/Duvall) 09/01/2015 – 08/31/2018
"Developing nanoparticle drug delivery strategies for inhibiting breast cancer- induced bone destruction"
Amount: $2,000,000
Source: : CDMRP/BCRP
Role: Co-investigator
Salary support: 2.1%

CURRENT AND COMPLETED INTRAMURAL RESEARCH SUPPORT

Principal Investigator at Vanderbilt

1. Breast Cancer SPORE (Pilot Project) 09/01/2007 – 09/01/2008
"The role of extracellular matrix properties in the behavior of osteolytic breast cancer cells"
Amount: $50,000
Source: NIH/NCI CA0998131-05
Role: PI
Collaborators: JA Sterling, JS Nyman
Salary support: 0%

Role other than Principal Investigator at Vanderbilt

2. VU Central Discovery Grant Program (Dickerson) 06/01/2006 – 05/31/2008
"In situ Observation of the Electric Field-Assisted Assembly of Nanocrystal Monolayers on Conducting Electrodes"
Amount: $100,000

Role: Co-investigator
Salary support: 0%

FELLOWSHIPS AND AWARDS RECEIVED BY STUDENTS

Graduate Students

Elizabeth Adolph
GAANN Fellowship
P.E.O. Scholar Award

Ushashi Dadwal
Schlumberger Future Faculty Fellowship

Madison McEnery
ORISE Research Fellowship
NSF Graduate Research Fellowship

Margarita Prieto
Dissertation Enhancement Award
Best Student Paper, Bone-Tec conference

Anne Talley
GAANN Fellowship

PENDING PROPOSALS

1. NIH/NCI
"Local Delivery of Hedgehog Pathway Inhibitors to Prevent Head and Neck Cancer Recurrence and Bony Invasion"
Budget: $1,250,000 (direct)
Personnel: JA Sterling (Administrative Multi PI), SA Guelcher (Multi PI)
Offset: 15%
Status: Pending
Submitted: 10/05/15
Period: 8/01/06 – 7/31/08

2. DOD/PRMRP
"Development of an Injectable, Settable, Resorbable Nanoceramic/Polymer Composite Bone Void Filler for Repair of Critical-Size Bony Defects"
Budget: $2,071,251
Personnel: SA Guelcher (PI), JC Wenke (Partnering PI), KN Kalpakci (Partnering PI)
Offset: 15%
Status: Pending
Submitted: 10/15/15
Period: 10/01/16 – 9/30/19

3. NSF/BME
"A 3D Bioreactor Model to Investigate Interactions between Cells and the Bone Microenvironment and Predict Drug Response"
Budget: $328,941
Personnel: SA Guelcher (PI), JA Sterling (Co-Investigator)
Offset: 0%
Status: Pending

Submitted: 10/20/15
Period: 7/01/16 - 6/30/19

4. NSF/BMAT
"Bioactive Nanocrystalline Hydroxyapatite/Poly(thioketal Urethane) Inorganic-Organic Hybrid Polymers for Healing of Weight-Bearing Bone Defects"
Budget: $333,126
Personnel: SA Guelcher (PI), JA Sterling (Co-Investigator)
Offset: 0%
Status: Pending
Submitted: 11/02/15
Period: 7/01/16 - 6/30/19

5. NIH/NCI Research Centers for Cancer Systems Biology Consortium (U54)
Center PIs: V Quaranta (VUMC Cancer Biology), T Yankeelov (Univ. of Texas)
Project 1: "Combining 3D and Computational Models to Investigate Microenvironmental Heterogeneity of Bone Metastases"
Budget: $1,500,000 (direct)
Personnel: SA Guelcher (Project Multi PI), JA Sterling (Project Multi PI)
Offset: 1 month
Status: Pending
Submitted: 11/20/15
Period: 10/01/16 – 9/30/21

4 Lectures

INVITED PRESENTATIONS

1. **SA Guelcher**, E de Beer, JL Anderson. Investigating the Mechanism of Aggregation of Colloidal Particles during Electrophoretic Deposition. Philips Research Laboratories, Eindhoven, The Netherlands, May 1998.
2. **SA Guelcher**, E de Beer, JL Anderson. Investigating the Mechanism of Aggregation of Colloidal Particles during Electrophoretic Deposition. Wageningen Agricultural University, The Netherlands, May 1998.
3. **SA Guelcher**, YuE Solomentsev, JL Anderson. Investigating the Mechanism of Aggregation of Colloidal Particles during Electrophoretic Deposition. Georgia Institute of Technology, Atlanta, GA, April 1999.
4. **SA Guelcher**, JS Kanel. Commercial Production of Biological Products from Marine Algae: Green Technology for Vitamins. West Virginia EPSCoR: The New Blueprint for Science and Technology, Ninth Annual Conference, January 28 – 29, 2002.
5. **SA Guelcher**, JO Hollinger. Orthopedic Biomaterials. 7th New Jersey Center for Biomaterials Symposium, New Brunswick, NJ, October 20 – 22, 2004.
6. **SA Guelcher**. Design of polyurethane biomaterials for orthopaedic clinical indications. Seminar presented at Clemson University, January 13, 2005.
7. **SA Guelcher**. Design of polyurethane biomaterials for orthopaedic clinical indications. Seminar presented at Auburn University, February 4, 2005.
8. **SA Guelcher**. Design of polyurethane biomaterials for orthopaedic clinical indications. Seminar presented at Carnegie Mellon University, February 20, 2005.
9. **SA Guelcher**. Design of polyurethane biomaterials for orthopaedic clinical indications. Seminar presented at University of Wyoming, March 13, 2005.

10. **SA Guelcher**. Design of polyurethane biomaterials for orthopaedic clinical indications. Seminar presented at Virginia Tech, April 22, 2005.
11. **SA Guelcher**. Poly(ester urethane)urea biomaterials for bone tissue engineering. Presented to the Center for Matrix Biology seminar series, Vanderbilt University, May 31, 2006.
12. **SA Guelcher**. Toward a synthetic biomimetic extracellular matrix: scaffold fabrication from poly(ester urethane)ureas. Presented to the VICBC Seminar Series, Vanderbilt University, June 8, 2006.
13. **SA Guelcher**. Career choices in academics. Presented at the 2006 NIBIB Training Grantee Workshop, Washington, DC, June 16, 2006.
14. **SA Guelcher**. Biomaterials for the treatment of orthopaedic injuries. Presented at the Advanced Technology Applications for Combat Casualty Care (ATACCC) Conference, St Pete Beach, FL, August 14 – 16, 2006.
15. **SA Guelcher**. Design and development of allograft bone/polyurethane composites. Seminar presented at Osteotech, Inc., Eatontown, NJ, January 16, 2007.
16. **SA Guelcher**. Design and development of polyurethane biomaterials for orthopaedic clinical indications. Seminar presented at West Virginia University, March 9, 2007.
17. **SA Guelcher**, F Papay. Bioneer Surgical – Technology Summary. Presented to Jumpstart, Inc., Cleveland, OH, March 15, 2007.
18. J Kohn, **SA Guelcher**. Armed Forces Institute for Regenerative Medicine. Seminar presented at the US Army Institute of Surgical Research, July 18, 2007.
19. **SA Guelcher**. Design and Development of Allograft Bone/Polyurethane Composites. Seminar presented at Osteotech, Inc., July 27, 2007.
20. **SA Guelcher**. Design and Development of Polyurethane Biomaterials for Orthopaedic Clinical Indications. Seminar Presented at Biomimetic Therapeutics, Inc., Franklin, TN, October 12, 2007.
21. **SA Guelcher**. Design and Development of Biodegradable Polyurethane Scaffolds for Tissue Engineering. Seminar Presented at Tennessee Technological University, November 15, 2007.
22. **SA Guelcher**. Biomaterials for bone regeneration and healing. Seminar presented at Vanderbilt University Department of Biomedical Engineering, October 15, 2008.
23. **SA Guelcher**. Release of BMP-2 and Tobramycin from Injectable, Biodegradable Polyurethane Scaffolds for Enhanced Bone Healing. Presented at the 9th New Jersey Symposium on Biomaterials Science and Regenerative Medicine, New Brunswick, NJ, October 29 – 31, 2008.
24. **SA Guelcher**. Developing a Dual-delivery Implant. Presented at the Extremity War Injuries V: Barriers to Return of Function and Duty, Washington, DC, January 27 – 29, 2010.
25. **SA Guelcher**. Polyurethane Scaffolds with Delivery of Biologically Active Molecules for Tissue Regeneration. Design of Medical Devices Conference, Minneapolis, MN, April 13 – 15, 2010.
26. **SA Guelcher**. Scaffolds and Drug Delivery Systems for Bone Regeneration. Seminar presented at University of Kentucky, October 6, 2010.
27. **SA Guelcher**. Matrix Rigidity Induces Osteolytic Gene Expression of Metastatic Breast Cancer Cells. Presented at Physics of Cancer Metastasis Meeting, Arlington, VA, November 1 – 2, 2010.
28. **SA Guelcher**. Scaffolds and Drug Delivery Systems for Bone Regeneration. Seminar presented at Cornell University, November 22, 2010.
29. **SA Guelcher**. Develop resorbable polyurethane/bone composite implants for fracture fixation and reconstruction of large cranio-orbital defects. AIBS Onsite Review of The Center for Military Biomaterials Research Program (CeMBR) at Rutgers, The State University of New Jersey, Piscataway, NJ, December 14, 2010.
30. **SA Guelcher**. Injectable biocomposites for repair of craniofacial bone. Presented at the McGowan Institute of Regenerative Medicine Annual Retreat (University of Pittsburgh), Pittsburgh, PA, March, 2011.
31. **SA Guelcher**. Injectable biocomposites and drug delivery systems for bone regeneration. Seminar at the US Army Institute of Surgical Research, San Antonio, TX, May 11, 2011.
32. **SA Guelcher**. Injectable biocomposites for repair of craniofacial bone. AFIRM Traveling Exchange Program (TEP), Rutgers University, Piscataway, NJ, July 12, 2011.

33. **SA Guelcher**. Low porosity injectable biocomposites incorporating rhBMP-2 enhance bone remodeling in a rabbit femoral plug model. ACS Annual Meeting, Denver, CO, August 28 - 31, 2011.
34. **SA Guelcher**. Injectable functional bone grafts. AFSOR Workshop on Regeneration and Remodeling of Structural Materials, Venice, ITALY, June 28-29, 2012.
35. **SA Guelcher**. Dual-purpose bone grafts for treatment of contaminated open fractures. Keynote Lecture, Chemical Engineering Graduate Student Symposium, Virginia Tech, Blacksburg, VA, April 12, 2012.
36. ***JM Page***, AR Merkel, JA Sterling, **SA Guelcher**. Effects of matrix rigidity on osteolytic gene expression in tumor cells. 244th ACS National Meeting & Exposition, Philadelphia, PA, August 19-23, 2012.
37. JA Sterling, ***JM Page***, AR Merkel, ***NS Ruppender***, **SA Guelcher**. Matrix Rigidity Alters TGF-β Signaling and Regulates Osteolytic Gene Expression by Tumor Cells. Society for Biomaterials Fall Symposium, New Orleans, LA, October 3-6, 2012.
38. **SA Guelcher**. Injectable Grafts for Bone Regeneration in Challenging Environments. Seminar presented at Kansas University, February 5, 2013.
39. **SA Guelcher**. Injectable Grafts for Bone Regeneration in Challenging Environments. Seminar presented at University of Memphis, April 5, 2013.
40. **SA Guelcher**. Injectable, settable lysine-derived polyurethane grafts for bone regeneration. 23rd Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures (GRIBOI), April 8 - 10, 2013, Boston, MA.
41. **SA Guelcher**. Injectable Grafts for Bone Regeneration in Challenging Environments. Seminar presented in the Department of Biomedical Engineering at Johns Hopkins University, Baltimore, MD, November 25, 2013.
42. **SA Guelcher**. Injectable Grafts for Bone Regeneration in Challenging Environments. Seminar presented in the Department of Biomedical Engineering at The University of Iowa, Ames, IA, December 12, 2013.
43. **SA Guelcher**. Translating Novel Biomaterials from Bench Top to Clinic. Scientific Seminar presented at the US Army Institute of Surgical Research, San Antonio, TX, February 5, 2014.
44. **SA Guelcher**. Microenvironmental Factors Regulating Establishment of Tumors in Bone. Presented at the NCI Strategic Workshop: Biomimetic Tissue Engineered Systems for Advancing Cancer Research, Rockville, MD, February 26, 2014.
45. **SA Guelcher**. Invited presentation for the Panel: Biomaterial Strategies for Craniomaxillofacial versus Orthopaedic Bone Defects. Society for Biomaterials Annual Meeting, Denver, CO, April 17, 2014.
46. **SA Guelcher**. Templated Scaffolds with Tunable Mechanical and Physical Properties Fabricated by Fused Deposition Modeling. International Forum on 3D Printing: Fundamentals and Biomedical Applications, Xi'an, China, August 28 - 29, 2014.
47. **SA Guelcher.** Clinical Applications of Novel Materials. 12th New Jersey Symposium on Biomaterials, New Brunswick, NJ, October 6-7, 2014.
48. **SA Guelcher**. Biodegradable Polyurethane Scaffolds for Bone Regeneration and Wound Healing. Invited presentation for the Polyurethanes Workshop. Society for Biomaterials Annual Meeting, Charlotte, NC, April 17, 2015.
49. **SA Guelcher**. A Transient Cell-Shielding Method for Viable MSC Delivery with Hydrophobic Scaffolds Polymerized *in situ*. Presented to the Novel Cellular Therapies Subsection of the Blood Bank and Cellular Therapies Professional Society. May 14, 2015.
50. **SA Guelcher.** Injectable and Settable Bone Grafts for Ridge Augmentation. Presented at the 25th Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures (GRIBOI). Toronto, CA, May 20, 2015.
51. **SA Guelcher**. Biomaterials-based interventions for Bone Tissue Engineering. Regenerative Medicine Essentials: From the Fundamentals to the Future. Wake Forest Institute of Regenerative Medicine, Winston Salem, NC, July 20 - 24, 2015.

52. **SA Guelcher**. Injectable Polyurethane Drug Delivery Systems. Merck & Company, West Point, PA, October 13 - 14, 2015.

CONFERENCE PRESENTATIONS

Oral and Poster Presentations

1. **SA Guelcher**, S-H Chiang. Hydrodynamic Study of a Novel Multi-Stage Loop-Flow Flotation Column. American Filtration Society Annual Technical Conference, Valley Forge, PA, April 1996.
2. **SA Guelcher**, YuE Solomentsev, JL Anderson. Self-Ordering of Colloidal Particles during Electrophoretic Deposition: A Hydrodynamic Model. ACS Colloid & Surface Science Symposium, Newark, DE, June 1997.
3. **SA Guelcher**, YuE Solomentsev, JL Anderson. Investigating the Mechanism of Aggregation of Colloidal Particles during Electrophoretic Deposition: An Electrochemical Model. ACS Colloid & Surface Science Symposium, State College, PA, June 1998.
4. **SA Guelcher**, YuE Solomentsev, PJ Sides, JL Anderson. The Effect of Surface-Induced Flows on Bubble and Particle Aggregation. Poster at Fourth Microgravity Fluid & Transport Phenomena Conference, Cleveland, OH, August 1998.
5. **SA Guelcher**, YuE Solomentsev, JL Anderson. Investigating the Mechanism of Aggregation of Colloidal Particles during Electrophoretic Deposition. AIChE Annual Meeting, Miami Beach, FL, November 1998.
6. **SA Guelcher**, YuE Solomentsev, JL Anderson. Electrokinetic Aggregation of Colloidal Particles on Electrodes. International Association of Colloid and Interface Scientists Meeting, Bristol, UK, July 2000.
7. **SA Guelcher**, EJ Beckman, JO Hollinger. A New Synthesis Strategy for Biodegradable Polyurethanes. 7th World Biomaterials Congress (poster), Sydney, Australia, May 16 -21, 2004.
8. **SA Guelcher**, JO Hollinger. Injectable Polyurethane Scaffolds for Bone Tissue Engineering. 7th New Jersey Center for Biomaterials Symposium, New Brunswick, NJ, October 20 – 22, 2004 (poster).
9. **SA Guelcher**, JO Hollinger. Injectable Polyurethane Scaffolds for Bone Tissue Engineering. AIChE Annual Meeting, Austin, TX, November 7 – 12, 2004.
10. **SA Guelcher**, JO Hollinger. Injectable Polyurethane Scaffolds for Bone Tissue Engineering. Society for Biomaterials Annual Meeting, Memphis, TN, April 27 – 30, 2005.
11. **SA Guelcher**, KM Gallagher, JE Didier, JO Hollinger. Injectable Polyurethane Scaffolds for Bone Tissue Engineering. Society for Biomaterials Annual Meeting, Memphis, TN, April 27 – 30, 2005
12. KA Dulaney, **SA Guelcher**, JO Hollinger, and AS Goldstein. Degradable Segmented Polyurethanes for Bone Tissue Engineering. AIChE Annual Meeting, Cincinnati, OH, October 30 – November 4, 2005.
13. **SA Guelcher**, KM Gallagher, JS Doctor, and JO Hollinger. Porous Polyurethane Foam Scaffolds for Bone Tissue Engineering. AIChE Annual Meeting, Cincinnati, OH, October 30 – November 4, 2005.
14. KO Dulaney, TW Pechar, GL Wilkes, **SA Guelcher**, JO Hollinger, AS Goldstein. High-modulus polyurethanes for bone tissue engineering. Poster presented at the Orthopaedic Research Society meeting, Chicago, IL, March 19 – 22, 2006.
15. A Srinivasan, KM Gallagher, S McBride, S Khetan, **SA Guelcher**, JO Hollinger. In vitro biocompatibility and biodegradation of poly(ester urethane)urea scaffolds. Poster presented at the Society for Biomaterials Annual Meeting, Pittsburgh, PA, April 26 – 29, 2006.
16. **SA Guelcher**, A Srinivasan, S McBride, JE Didier, and JO Hollinger. In vitro biocompatibility and biodegradation of two-component cast poly(ester urethane)s. Poster presented at the Regenerate World Congress on Tissue Engineering and Regenerative Medicine, Pittsburgh, PA, April 24 – 27, 2006.

17. CA Bashur, RD Shaffer, **SA Guelcher**, AS Goldstein. Electrospun polyurethanes for ligament tissue engineering. Poster presented at the Biomedical Engineering Society Annual Meeting, Chicago, IL, October 11 – 14, 2006.
18. CA Bashur, MS Mills, **SA Guelcher**, AS Goldstein. Electrospun polyurethanes and bone marrow stromal cells for ligament tissue engineering. Presented by AS Goldstein at the AIChE Annual Meeting, San Francisco, CA, November 12 – 17, 2006.
19. ***AE Hafeman***, **SA Guelcher**. Biodegradable, injectable poly(ester urethane)urea delivery systems for bone tissue engineering. Presented at the AIChE Annual Meeting, San Francisco, CA, November 12 – 17, 2006.
20. KO Dulaney, **SA Guelcher**, AS Goldstein. Novel polyurethane porous foam scaffolds for bone tissue engineering applications. Presented by AS Goldstein at the AIChE Annual Meeting, San Francisco, CA, November 12 – 17, 2006.
21. ***KL Zienkiewicz***, **SA Guelcher**. Segmented poly(ester urethane)urea elastomers with biodegradable hard and soft segments. Presented at the AIChE Annual Meeting, San Francisco, CA, November 12 – 17, 2006.
22. **SA Guelcher**, A Srinivasan, JO Hollinger. Biodegradable poly(ester urethane)urea biomaterials for applications in combat casualty care. Poster presented at the 25th Army Science Conference, Orlando, FL, November 27 – 30, 2006.
23. A Srinivasan, J Kwan, E Walsh, S McBride, ***AE Hafeman***, **SA Guelcher**, JO Hollinger. In Vitro Mineralization of PEUUR and PEUUR/DBM Composite Foams. Poster presented at the Society for Biomaterials Annual Meeting, Chicago, IL, April 18 – 21, 2007.
24. AE Hafeman, JM Davidson, and **SA Guelcher**. Effects of Polyol, Isocyanate, and Additives on Poly(ester urethane)urea Scaffolds: Material and in vivo Histological Properties. Poster presented at the American Chemical Society Annual Meeting, Boston, MA, August 19 – 23, 2007.
25. KD Kavlock, **SA Guelcher**, AS Goldstein. Effect Of Scaffold Modulus On Osteogenic Differentiation Of Bone Marrow Stromal Cells. Poster presented at the Biomedical Engineering Society Annual Meeting, Los Angeles, CA, September 26 – 29, 2007.
26. CA Bashur, RD Shaffer, JJ Yoo, **SA Guelcher**, AS Goldstein. Ligament Development On Electrospun Elastomeric Polyurethane Scaffolds. Poster presented at the Biomedical Engineering Society Annual Meeting, Los Angeles, CA, September 26 – 29, 2007.
27. ***JE Dumas*** and **SA Guelcher**. Resorbable Polyurethane/Bone Composites for Bone Tissue Engineering. Presented at the AIChE Annual Meeting, Salt Lake City, UT, November 5 – 9, 2007.
28. ***AE Hafeman***, ***K Zienkiewicz***, J Davidson, **SA Guelcher**. In vivo Characterization of Biodegradable Polyurethane Scaffolds in a Wound Healing Model. Presented at the AIChE Annual Meeting, Salt Lake City, UT, November 5 – 9, 2007.
29. ***AE Hafeman***, E Carney, B Litzner, ***K Zienkiewicz***, *LI Hochhauser*, JM Davidson, C Stratton, **SA Guelcher**. Release of Antibiotic from Injectable, Biodegradable Polyurethane Scaffolds for Enhanced Bone Fracture Healing. Orthopedic Research Society Annual Meeting, San Francisco, CA, March 2 – 5, 2008, San Francisco, CA. Poster.
30. ***JE Dumas***, *TE Davis*, A Srinivasan, JO Hollinger, and **SA Guelcher**. Injectable Polyurethane/ Mineralized Bone Powder Composites. Orthopedic Research Society Annual Meeting, San Francisco, CA, March 2 – 5, 2008, San Francisco, CA. Poster.
31. ***JE Dumas***, *TE Davis*, A. Srinivasan, C Ho, R Desai, JO Hollinger, and *SA Guelcher*. Resorbable Polyurethane/Bone Composites for Bone Tissue Engineering. World Biomaterials Congress, May 28 – June 1, 2008, Amsterdam, NETHERLANDS. Oral.
32. ***AE Hafeman***, E Carney, B Litzner, ***K Zienkiewicz***, *LI Hochhauser*, JM Davidson, C Stratton, **SA Guelcher**. Release of BMP-2 and Tobramycin from Injectable, Biodegradable Polyurethane Scaffolds for Enhanced Bone Fracture Healing. World Biomaterials Congress, May 28 – June 1, 2008, Amsterdam, NETHERLANDS. Oral.
33. ***AE Hafeman***, ***K Zienkiewicz***, JM Davidson, **SA Guelcher**. Synthesis and in vivo characterization of injectable and biodegradable polyurethane scaffolds in a wound healing model. TERMIS-EU

Annual Meeting, June 22 – 26, 2008, Alfandega, PORTUGAL. Poster. Published in Tissue Engineering Part A 14(5): 910-11.

34. ***NS Ruppender***, JA Sterling, JS Nyman, JF O'Keefe, GR Mundy, and **SA Guelcher**. Effects of Extracellular Matrix Properties and Elastic Modulus on the Expression of parathyroid hormone-related peptide (PTHrP) by Human Breast Cancer Cells. ASBMR Annual Meeting, September 12 – 16, 2008, Montreal, CANADA. Poster.
35. ***AE Hafeman***, ***KJ Zienkiewicz***, JM Davidson, and **SA Guelcher**. Injectability of Biodegradable, Porous Polyurethane Scaffolds for Tissue Regeneration. 9th New Jersey Symposium on Biomaterials Science and Regenerative Medicine, October 29 – 31, 2008, New Brunswick, NJ. Poster.
36. ***JE Dumas***, **SA Guelcher**. Resorbable Polyurethane/Bone Composites for Bone Tissue Engineering. AIChE Annual Meeting, November 17 – 21, 2008, Philadelphia, PA. Oral.
37. ***AE Hafeman***, ***B Li***, ***KL Zienkiewicz***, and **SA Guelcher**. Delivery of Antibiotics and BMP-2 from Biodegradable Polyurethane Scaffolds. AIChE Annual Meeting, November 17 – 21, 2008, Philadelphia, PA. Oral.
38. ***AE Hafeman***, JO Hollinger, **SA Guelcher**. Release of BMP-2 and tobramycin from injectable, biodegradable polyurethane scaffolds for enhanced bone fracture healing. Army Science Conference, December 1 – 4, 2008, Orlando, FL. Poster.
39. ***AE Hafeman***, ***KL Zienkiewicz***, ***B Li***, JM Davidson, **SA Guelcher**. Injectable Biodegradable Polyurethane Scaffolds for Tissue Regeneration. TERMIS-NA Annual Conference and Exposition, December 7 – 10, San Diego, CA. Oral.
40. ***AE Hafeman***, ***KL Zienkiewicz***, T Yoshii, GE Gutierrez, GR Mundy, **SA Guelcher**. Injectable, Biodegradable Polyurethane Scaffolds With Local Lovastatin Delivery For Enhanced Bone Regeneration. TERMIS-NA Annual Conference and Exposition, December 7 – 10, 2009, San Diego, CA. Poster.
41. ***B Li***, **SA Guelcher**. Controlled Release of BMP-2 from Injectable Polyurethane Scaffolds. TERMIS-NA Annual Conference and Exposition, December 7 – 10, 2009, San Diego, CA. Poster.
42. ***SA Tanner***, ***B Li***, J Kim, T Jacobs, S Bhattacharyya, JO Hollinger, **SA Guelcher**. Injectable Allograft Bone/Polymer Composite Scaffolds for the Treatment of Craniofacial Bone Defects. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 13 – 15, 2009, St Pete Beach, FL. Oral.
43. ***B Li***, J Kim, A Karunanidhi, L Schutte, JO Hollinger, **SA Guelcher**. Sustained Release of BMP-2 from Polyurethane Scaffolds Promotes New Bone Formation in Rat Femoral Defect. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 13 – 15, 2009, St Pete Beach, FL. Oral.
44. J Kim, ***SA Tanner***, **SA Guelcher**, JO Hollinger. Cell Attachment and Differentiation of Osteoprogenitor Cells on Injectable Bone Particle (BP)/Polyurethane (PUR) Composites in Three Dimensional (3D) Cell Culture. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 13 – 15, 2009, St Pete Beach, FL. Poster.
45. A Karunanidhi, J Kim, ***B Li***, L Shutte, **SA Guelcher**, JO Hollinger. Osteogenic Differentiation of Human Mesenchymal Stem Cell in Response to Exogenous or Released Recombinant Human Bone Morphogenetic Protein 2 (BMP-2) from Polyurethane (PUR) Composites for Treatment of Craniofacial Bone Defects. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 13 – 15, 2009, St Pete Beach, FL. Poster.
46. T Yoshii, ***AE Hafeman***, JS Nyman, ***KL Zienkiewicz***, GE Gutierrez, GR Mundy, **SA Guelcher**. Injectable, Biodegradable Polyurethane Scaffolds With Local Lovastatin Delivery For Enhanced Bone Regeneration. Orthopaedic Research Society Annual Meeting, February 23 – 25, 2009. Oral.
47. ***AE Hafeman***, ***KL Zienkiewicz***, T Yoshii, JM Davidson, **SA Guelcher**. Injectable, Biodegradable, Porous Polyurethane Scaffolds for Tissue Regeneration. Society for Biomaterials Annual Meeting, April 22 – 25, 2009. San Antonio, TX. Oral.

48. ***B Li***, T Yoshii, **SA Guelcher**. Controlled Delivery of BMP-2 from Polyurethane Scaffolds Promotes New Bone Formation in Rat Femoral Defect. Society for Biomaterials Annual Meeting, April 22 – 25, 2009. San Antonio, TX. Oral.
49. ***B Li***, JM Davidson, **SA Guelcher**. Local Delivery of PDGF-BB from Polyurethane Scaffold Enhances Tissue Regeneration in Rat Excisional Wounds. Society for Biomaterials Annual Meeting, April 22 – 25, 2009. San Antonio, TX. Oral.
50. ***NS Ruppender***, JA Sterling, PD Boyer, GR Mundy, **SA Guelcher**. Effects of Extracellular Matrix Properties on Osteolytic Potential of Human Breast Cancer Cells. Society for Biomaterials Annual Meeting, April 22 – 25, 2009. San Antonio, TX. Poster.
51. ***AE Hafeman***, ***B Li***, JM Davidson, **SA Guelcher**. Injectable, Biodegradable, Polyurethane Scaffolds for Tissue Restoration. 5th Joint Meeting of The European Tissue Repair Society and The Wound Healing Society, August 25 – 29, 2009. Limoges, FRANCE. Oral. Published in Wound Repair and Regeneration 17(4): A68, 2011.
52. ***B Li***, KV Brown, JC Wenke, **SA Guelcher**. Dual Delivery of Growth Factor and Antibiotic from Polyurethane Scaffold Improves Tissue Regeneration in Infected Bone Wounds. 2nd TERMIS World Congress, August 31 - September 3, 2009. Seoul, KO. Oral.
53. ***SA Tanner, B Li***, **SA Guelcher**. Delivery of Bone Morphogenetic Protein from Injectable Allograft Bone/Polymer Composites for the Treatment of Craniofacial Bone Defects. 2nd TERMIS World Congress, August 31 - September 3, 2009. Seoul, KO. Oral.
54. ***JE Dumas***, GE Holt, **SA Guelcher**. Resorbable Mineralized Bone Particle/Polyurethane Composites for Bone Tissue Engineering. AIChE Annual Meeting, November 9 – 13, 2009. Nashville, TN. Oral.
55. ***JE Dumas,*** K Zienkiewicz***, SA Tanner, EM Prieto,*** S Bhattacharyya***,*** **SA Guelcher**. Injectable Allograft Bone-Polyurethane Composite Foam Scaffolds: Tuning Mechanical Properties by Controlling Scaffold Porosity. AIChE Annual Meeting, November 9 – 13, 2009. Nashville, TN. Oral.
56. CA Bashur, **SA Guelcher**, AS Goldstein. Effect of Uniaxial Stretch on ECM Expression by Ligament Progenitor Cells on Electrospun Fibrous Meshes. AIChE Annual Meeting, November 9 – 13, 2009. Nashville, TN. Oral.
57. ***JE Dumas***, KJ Zienkiewicz, PB Baer, JC Wenke, **SA Guelcher**. Mineralized Bone Particle/ Polyurethane Composite Bone Void Filler with Recombinant Human Bone Morphogenetic Protein. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 11 – 14, 2010, St Pete Beach, FL. Oral.
58. ***B Li***, KV Brown, DS Perrien, T Guda, JC Wenke, **SA Guelcher**. Infected Bone Wound Healing Achieved by Dual Delivery of Vancomycin & rhBMP-2 from Polyurethanes. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 11 – 14, 2010, St Pete Beach, FL. Oral.
59. ***EM Prieto***, K Zienkiewicz, DC Harris, **SA Guelcher**. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 11 – 14, 2010, St Pete Beach, FL. Poster.
60. T Yoshii, ***AE Hafeman***, JS Nyman, J Esparza, D Spengler, GR Mundy, **SA Guelcher**, G Gutierrez. Local Lovastatin Injection Enhances Bone Regeneration Using Biodegradable Polyurethane Scaffolds. Orthopaedic Research Society Annual Meeting, March 6 - 9, 2010. New Orleans, LA. Oral.
61. KV Brown, ***B Li***, T Guda, **SA Guelcher**, JC. Wenke. Decreasing Complications in Open Fractures with a Novel Bone Graft. Orthopaedic Research Society Annual Meeting, March 6 - 9, 2010. New Orleans, LA. Poster.
62. ***JE Dumas***, **SA Guelcher**. Resorbable Mineralized Bone Particle/Polyurethane Composites for BoneTissue Engineering. Orthopaedic Research Society Annual Meeting, March 6 - 9, 2010. New Orleans, LA. Poster.
63. ***EM Prieto***, K Zienkiewicz, DC Harris, **SA Guelcher**. Improvement of Interfacial Compatibility in Polyurethane/Tricalcium Phosphate Composite Bone Cements Through Filler Surface Modification. Society for Biomaterials Annual Meeting, April 21 – 24, 2010. Seattle, WA. Poster.

64. ***B Li***, KV Brown, JC Wenke, **SA Guelcher**. Sustaining the Release of Vancomycin from Polyurethane Scaffold for Infection Control. Society for Biomaterials Annual Meeting, April 21 – 24, 2010. Seattle, WA. Oral.
65. ***B Li***, KV Brown, JC Wenke, **SA Guelcher**. Dual delivery of Vancomycin and rhBMP-2 from Polyurethane Implants for Contaminated Bone Wound Healing. Society for Biomaterials Annual Meeting, April 21 – 24, 2010. Seattle, WA. Oral.
66. ***AE Hafeman***, T Yoshii, JS Nyman, JM Esparza, GR Mundy, GE Gutierrez, **SA Guelcher**. Local Lovastatin Injection Enhances Bone Regeneration Using Biodegradable Polyurethane Scaffolds. Society for Biomaterials Annual Meeting, April 21 – 24, 2010. Seattle, WA. Oral.
67. ***JE Dumas***, KJ Zienkiewicz, PB Baer, and **SA Guelcher**. Injectable Allograft Bone/Polymer Composite Bone Void Filler with Recombinant Human Bone Morphogenetic Protein. Society for Biomaterials Annual Meeting, April 21 – 24, 2010. Seattle, WA. Oral.
68. ***NS Ruppender***, JA Sterling, TJ Martin, GR Mundy, **SA Guelcher**. Skeletal Rigidity Enhances TGF-beta Effects on Cancer Cell Expression of Osteolytic Factors. CABS Cancer and Bone Society, 10th International Conference on Cancer Induced Bone Disease, Sheffield, United Kingdom, Sep 22 – 25, 2010. Abstract published as Bone 48(1): S39, 2011.
69. KV Brown, ***B Li***, T Guda, DS Perrien, **SA Guelcher**, JC. Wenke. Decreasing Complications in Open Fractures with a Novel Bone Graft. Orthopaedic Trauma Association Annual Meeting, October 14 – 16, 2010. Baltimore, MD. Oral.
70. ***EM Prieto***, KL Zienkiewicz, DC Harris, **SA Guelcher**. Effects of Bone Surface Composition on the Mechanical Properties and Biocompatibility of Polyurethane/Allograft Bone Composite Cements. AIChE Annual Meeting, November 7 – 12, 2010. Salt Lake City, UT. Oral.
71. ***NS Ruppender***, JA Sterling, GR Mundy, **SA Guelcher**. Invasive Behavior in Osteolytic Metastatic Cancers is Dictated by Mechanical Cues. AIChE Annual Meeting, November 7 – 12, 2010. Salt Lake City, UT. Oral.
72. Parekh A, ***Ruppender NS***, Branch KM, Sewell-Loftin MK, Lin J, Boyer PD, Candiello JE, Merryman WD, **Guelcher SA**, Weaver, AM. Cancer cells sense a wide range of mechanical rigidities and tune the invasive phenotype. American Society for Cell Biology 49th Annual Meeting, Philadelphia, PA, December, 2010.
73. ***JE Dumas***, EM Prieto, KL Zienkiewicz, GE Holt, **SA Guelcher**. Low Porosity Injectable (Reactive-Allograft-Bone/Polyurethane) Composites Incorporating rhBMP-2 Enhance Bone Remodeling in a in a Rabbit Femoral Plug Model. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 18 – 20, 2011, St Pete Beach, FL. Oral.
74. ***EM Prieto***, ***JE Dumas***, KJ Zienkiewicz, JC Wenke, R Hale, PB Baer, **SA Guelcher**. Injectable Allograft Bone/Polymer Composite Bone Void Filler for Repair of Calvarial Defects. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 18 – 20, 2011, St Pete Beach, FL. Oral.
75. ***BH Lee***, **SA Guelcher**. Gel microstructure regulates proliferation and differentiation of MC3T3-E1 cells encapsulated in alginate beads. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 18 – 20, 2011, St Pete Beach, FL. Oral.
76. ***BH Lee***, **SA Guelcher**. Local cell delivery from injectable biodegradable polymeric scaffolds. Armed Forces Institute for Regenerative Medicine (AFIRM) All-Hands Meeting, January 18 – 20, 2011, St Pete Beach, FL. Poster.
77. KV Brown, ***B L***, T Guda, ***B-H Lee***, SA Guelcher, JC Wenke. Dual-Purpose Bone Grafts Reduce Infection and Improve Healing. American Academy of Orthopaedic Surgeons Annual Meeting, February 15 – 19, 2011, San Diego, CA. Oral.
78. A Parekh, ***NS Ruppender***, KM Branch, **SA Guelcher,** and AM Weaver. Invasive phenotype is tuned by substrate rigidity: Implications for basement membrane invasion. ACS Annual Meeting, March 27 - 31, 2011, Anaheim, CA. Oral. Published as Abstracts of papers of the American Chemical Society (241): 57-COLL.
79. ***JE Dumas***, ***EM Prieto***, J Bible, GE Holt, **SA Guelcher**. Low porosity injectable biocomposites incorporating rhBMP-2 enhance bone remodeling in a rabbit femoral plug model. 21st

Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures. April 5 - 7, 2011, Boston, MA. Oral.

80. EA Adolph, AE Hafeman, JM Davidson, LB Nanney, SA Guelcher. Injectable polyurethane scaffolds delay wound contraction and support cellular infiltration and remodeling in rat excisional wounds. Wound Healing Society Annual Meeting, April 14 - 17, 2011, Dallas, TX. Oral. Published in Wound Repair and Regeneration 19(2): A9, 2011.
81. CE Nelson, MK Gupta, ***EJ Adolph***, **SA Guelcher**, CL Duvall. "Smart", Sustained Local Delivery of siRNA from an Injectable Scaffold. Society for Biomaterials Annual Meeting, April 13 - 16, 2011, Orlando, FL. Oral.
82. ***B-H Lee, B Li***, **SA Guelcher**. Injectable Alginate Microcapsule/Polyurethane Composite Scaffolds for Cell Therapy. Society for Biomaterials Annual Meeting, April 13 - 16, 2011, Orlando, FL. Poster
83. ***JE Dumas***, P Brown Baer, JC Wenke, RG Hale, **SA Guelcher**. Injectable allograft bone/polymer bone void filler for repair of calvarial defects. 4th International Conference on Tissue Engineering, May 31 - June 5, 2011, Chania, Crete, GREECE. Rapid fire oral and poster presentations.
84. ***JE Dumas***, ***EM Prieto***, J Bible, GE Holt, **SA Guelcher**. Low porosity injectable biocomposites incorporating rhBMP-2 enhance bone remodeling in a rabbit femoral plug model. 4th International Conference on Tissue Engineering, May 31 - June 5, 2011, Chania, Crete, GREECE. Rapid fire oral and poster presentations.
85. ***BH Lee***, **SA Guelcher**. Gel microstructure regulates proliferation and differentiation of MC3T3 cells encapsulated in alginate beads. 4th International Conference on Tissue Engineering, May 31 - June 5, 2011, Chania, Crete, GREECE. Poster.
86. PR Brown Baer, DT Silliman, JC Wenke, **SA Guelcher**, ***JE Dumas***, RG Hale. Influence of Porosity and rh-BMP2 on Healing Using an Injectable Bone Regenerative Scaffold. Advanced Technology Applications for Combat Casualty Care (ATACCC) Conference, August 15 - 17, 2011, Tampa, FL. Poster.
87. A Zachman, ***J Page***, C Bronikowski, **S Guelcher**, H-J Sung. Macrophage activation through oxidative response to biodegradable polyurethane scaffolds with functional peptide. Biomedical Engineering Society Annual Meeting, October 12-15, 2011, Hartford, CT. Poster.
88. A Zachman, C Bronikowski, O Ortiz, ***K Zienkiewicz***, S Crowder, **S Guelcher**, J Kohn, H Kleinman, H-J Sung. Inflammatory response-mediated regulation of angiogenesis in bioactive hydrogels. Biomedical Engineering Society Annual Meeting, October 12-15, 2011, Hartford, CT. Poster.
89. ***EM Prieto, JE Dumas***, J Bible, GE Holt, **SA Guelcher**. Injectable weight-bearing biocomposites for bone regeneration. International Bone-Tissue-Engineering Congress, October 12 - 15, 2011, Hannover, GERMANY. Oral. * EM Prieto won the Outstanding Oral Presentation Award *
90. ***EJ Adolph***, JM Davidson, LB Nanney, **SA Guelcher**. Injectable Polyurethane Composite Scaffolds Delay Wound Closure and Support Cellular Infiltration and Remodeling In Rat Excisional Wounds. AIChE Annual Meeting, October 16 - 21, 2011, Minneapolis, MN. Oral.
91. ***EJ Adolph***, JM Davidson, LB Nanney, **SA Guelcher**. Effects of Scaffold Mechanical Properties On the Delivery of Stromal Cell-Derived Factor-1 From Polyurethane Scaffolds In Rat Cutaneous Wounds. AIChE Annual Meeting, October 16 - 21, 2011, Minneapolis, MN. Oral.
92. ***EM Prieto, EJ Adolph***, **SA Guelcher**. Biomaterials reaching high schools through students and educators. AIChE Annual Meeting, October 16 - 21, 2011, Minneapolis, MN. Oral.
93. ***EM Prieto***, *EL von Stein*, **SA Guelcher**. In vitro effect of polyurethane composites with surface modified fillers on the osteoclastic differentiation process. AIChE Annual Meeting, October 16 - 21, 2011, Minneapolis, MN. Oral.
94. RW Johnson, AR Merkel, ***NS Ruppender***, **SA Guelcher**, LM Matrisian, JA Sterling. Bone stiffness drives Wnt signaling regulation of Gli2 in osteolytic breast cancer cells. Cancer in Bone Society (CABS) Meeting, November 30 - December 3, 2011, Chicago, IL.
95. ***NS Ruppender***, AR Merkel, **SA Guelcher**, and JA Sterling. Integrin Dependent Mechanotransduction Signaling Regulates PTHrP Expression in Breast Cancer Cells. Cancer in Bone Society (CABS) Meeting, November 30 - December 3, 2011, Chicago, IL. Oral.

96. PR Brown Baer, ***JE Dumas***, JC Wenke, DT Silliman, COL RG Hale, **SA Guelcher**. Influence of Porosity and rhBMP-2 on Healing Using an Injectable Bone Regenerative Scaffold. TERMIS NA Meeting, December 11 - 14, 2011, Houston, TX. Poster.
97. ***AD Talley***, ***EM Prieto***, ***KJ Zienkiewicz***, DT Silliman, JC Wenke, P BrownBaer, **SA Guelcher**. Injectable Polymer/β-TCP Biocomposite Delivery Systems for rhBMP-2. AFIRM All-hands meeting, February 14 - 15, 2012, St. Pete Beach, FL. Oral.
98. ***AD Talley***, ***EM Prieto***, ***KJ Zienkiewicz***, DT Silliman, JC Wenke, P BrownBaer, K Kalpakci, and **SA Guelcher**. Commercialization of an Injectable, Settable Biocomposite Bone Void Filler. AFIRM All-hands meeting, February 14 - 15, 2012, St. Pete Beach, FL. Poster.
99. ***AD Talley***, ***EM Prieto***, DT Silliman, JC Wenke, P BrownBaer, **SA Guelcher**. Injectable, Settable Polymer/β-TCP Bone Grafts for Delivery of rhBMP-2. 22nd Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures (GRIBOI), May 10-12, 2012, Uppsala, SWEDEN. Oral.
100. ***EJ Adolph***, F Yu, LB Nanney, JM Davidson, and **SA Guelcher**. Effects of Delivery of Recombinant Human Stromal Cell-Derived Factor-1 from Polyurethane Scaffolds with Different Young's Moduli on Cutaneous Healing in Rat Excisional Wounds. 9th World Biomaterials Congress, June 1 - 5, 2012. Chengdu, CHINA. Poster.
101. ***R Guo*** and **SA Guelcher**. Injectable Polyurethane with Degradable Calcium Alginate Beads as a Cell Delivery System for Tissue Repair. 9th World Biomaterials Congress, June 1 - 5, 2012. Chengdu, CHINA. Oral.
102. A Zachman, ***JM Page***, A Boone, G Prabhakar, **SA Guelcher**, HJ Sung. Regulation of adhesion-dependent apoptosis in macrophages by PEG-containing polyurethane films. BMES Annual Meeting, Seattle, WA, September 25-28, 2012. Poster
103. C Nelson, A Kim, ***EJ Adolph***, M Gupta, F Yu, JM Davidson, **SA Guelcher**, C Duvall. Injectable tissue engineering scaffolds that mediate efficient gene silencing in vivo. BMES Annual Meeting, Seattle, WA, September 25-28, 2012. Oral
104. J Martin, M Gupta, ***JM Page***, ***EJ Adolph***, **SA Guelcher**, C Duvall. Synthesis of a novel injectable, ROS-degradable tissue engineering scaffold. BMES Annual Meeting, Seattle, WA, September 25-28, 2012. Poster
105. C Duvall, C Nelson, H Li, S Yu, JM Davidson, **SA Guelcher**, T Giorgio. Local and targeted siRNA delivery technologies. BMES Annual Meeting, Seattle, WA, September 25-28, 2012. Oral
106. R Allen, M Yoshida, W Wu, L Volpatti, **SA Guelcher**, Y Wang. Improved design for cell-free, fast degrading synthetic artery grafts. BMES Annual Meeting, Atlanta, GA, October 24 - 27, 2012. Oral
107. CA Krueger, J Penn-Barwell, **SA Guelcher**, JC Wenke. Antibiotic Release from Scaffold Prevents the Bone Graft from Causing Infection. Orthopaedic Trauma Association Annual Meeting, October 4 - 6, 2012. Minneapolis, MN. Oral..
108. A Zachman, ***JM Page***, C Bronikowski, A Boon, **SA Guelcher**, H-J Sung. Macrophage response to biodegradable polyurethane scaffolds with functional peptide treatment. Society for Biomaterials Fall Symposium, New Orleans, LA, October 3-6, 2012.
109. ***AJ Harmata***, **SA Guelcher**. Effects of Surface Modification of 45S5 Bioactive Glass on Bioactivity and Mechanical Properties of Polymeric Biocomposites. Society for Biomaterials Fall Symposium, New Orleans, LA, October 3-6, 2012. Oral
110. ***EJ Adolph***, F Yu, LB Nanney, JM Davidson, SA Guelcher. Effects of Delivery of Recombinant Human Stromal Cell-Derived Factor-1 from Polyurethane Scaffolds with Different Degradation Rates on Cutaneous Healing in Rat Excisional Wounds. Society for Biomaterials Fall Symposium, New Orleans, LA, October 3-6, 2012.
111. ***EM Prieto***, ***AD Talley***, ***KJ Zienkiewicz***, K Kalpakci, **SA Guelcher**. Effect of Matrix Particle Size and Loading On the Overall Performance of Injectable Allograft/Polyurethane Composite Bone Void Fillers. AIChE Annual Meeting, Pittsburgh, PA, October 29 - November 2, 2012.
112. ***EM Prieto***, *EL Von Stein*, **SA Guelcher**. Osteoclastic Resorption of Mineralized Fillers in the Presence of Bone Morphogenetic Protein-2. AIChE Annual Meeting, Pittsburgh, PA, October 29 - November 2, 2012.

113. ***EM Prieto, EJ Adolph***, **SA Guelcher**. Investigating Cooperative Learning Grouping Strategies in an Introductory Engineering Course. AIChE Annual Meeting, Pittsburgh, PA, October 29 - November 2, 2012. Oral.
114. ***JM Page***, A Merkel, JA Sterling, **SA Guelcher**. 3D Polyurethane Scaffolds (3D-PURS) with Defined Architecture and Rigidity for Analysis of Tumor-Induced Bone Disease. Cancer-Induced Bone Disease Annual Meeting, Lyon, FR, November 15 - 17, 2012.
115. ***AD Talley***, T Guda, DT Silliman, P Brown-Baer, JC Wenke, **SA Guelcher**. Injectable Biocomposite Grafts Demonstrate Effective BMP-2 Delivery for Bone Healing. Orthopaedic Research Society Annual Meeting, San Antonio, TX, January 26 - 29, 2013. Poster.
116. ***AJ Harmata***, CL Ward, JC Wenke, **SA Guelcher**. Remodeling of Settable Composites with Initial Bone-like Strength. Hilton Head Workshop, Regenerative Medicine: Technologies Enabling Novel Therapies, Hilton Head, SC, March 20-23, 2013. Oral.
117. ***AD Talley***, ***EM Prieto***, T Guda, P Brown Baer, TD Silliman, **SA Guelcher**. Injectable Polymer/β-TCP Biocomposite Delivery Systems for rhBMP-2. Society for Biomaterials Annual Meeting, Boston, MA, April 10 - 13, 2013. Oral.
118. ***R Guo***, CL Ward, JC Wenke, **SA Guelcher**. Injectable Scaffolds with Degradable Calcium Alginate Beads as a Cell Delivery System for Tissue Repair. Society for Biomaterials Annual Meeting, Boston, MA, April 10 - 13, 2013. Oral.
119. ***AJ Harmata***, CL Ward, JC Wenke, **SA Guelcher**. In Vivo Remodeling of 45S5 Bioactive Glass/ Polyurethane Biocomposites with Initial Bone-like Mechanical Properties. Society for Biomaterials Annual Meeting, Boston, MA, April 10 - 13, 2013. Oral.
120. ***EM Prieto***, CJ Sanchez Jr, CA Kruger, KJ Zienkiewicz, DR Romano, KS Akers, SK Hardy, RL Woodburry, JC Wenke, **SA Guelcher**. Local Delivery of D-Amino Acids Reduce Bacterial Burden in Contaminated Rat Segmental Defects. Society for Biomaterials Annual Meeting, Boston, MA, April 10 - 13, 2013. Oral.
121. S Cannonier, ***JM Page***, AR Merkel, **SA Guelcher**, JA Sterling. Matrix Rigidity Regulates Osteolytic Gene Expression in Oral Squamous Cell Carcinomas. Society for Biomaterials Annual Meeting, Boston, MA, April 10 - 13, 2013. Poster.
122. ***EJ Adolph***, CE Nelson, JM Shannon, CL Duvall, **SA Guelcher**. Lyophilized Poly(ethylene glycol-b-(dimethylaminoethyl methacrylate-stat-butyl methacrylate))-DNA Nanoparticles for Nonviral Gene Therapy. Society for Biomaterials Annual Meeting, Boston, MA, April 10 - 13, 2013. Poster.
123. ***AJ Harmata***, S Uppuganti, JS Nyman **SA Guelcher**. Effects of surface modification of 45S5 bioactive glass on dynamic compressive fatigue mechanical properties of polymeric biocomposites. 23rd Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures (GRIBOI), April 8 - 10, 2013, Boston, MA. Oral.
124. ***AD Talley***, KJ Zienkiewicz, SS Funk, J Dasgupta, JC Wenke, JM Davidson, GE Holt, **SA Guelcher**. *In vivo* rhBMP-2 Release from Degradable Polyurethane Biocomposites. 23rd Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures (GRIBOI), April 8 - 10, 2013, Boston, MA. Oral.
125. ***EM Prieto***, **SA Guelcher**. Effects of rhBMP-2 and mineralized matrix composition over osteoclastic differentiation and resorptive activity. 23rd Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures (GRIBOI), April 8 - 10, 2013, Boston, MA. Oral.
126. ***R Guo***, CL Ward, CL Duvall, JM Davidson, JC Wenke, **SA Guelcher**. Injectable polyurethane/ alginate composite scaffolds for cell delivery. 2013 eCM XIV: Stem & Progenitor Cells for Musculoskeletal Regeneration, Davos, Switzerland June 23 - 25, 2013.
127. CE Nelson, A Kim, A Hannah, ***EJ Adolph***, MK Gupta, F Yu, JM Davidson, **SA Guelcher**, CL Duvall. Tunable and Sustained Scaffold-based Gene Silencing In Vivo. The Controlled Release Society Annual Meeting, Honolulu, HI, July 21 - 24, 2013. Poster.
128. R Guo, CL Ward, **SA Guelcher**. Injectable Scaffolds with Degradable Calcium Alginate Beads as a Cell Delivery System for Tissue Repair. MSC 2013 - Adult Stem Cell Therapy and Regenerative Medicine, Cleveland, OH, August 19 - 21, 2013. Poster.

129. EJ Adolph, CE Nelson, JM Shannon, CL Duvall, SA Guelcher. Enhanced Stability and Activity of pH-sensitive Self-assembled Diblock Copolymer/Plasmid Complexes. BMES Annual Meeting, Seattle, WA, September 25 - 28, 2013. Oral.
130. CA Krueger, C Sanchez, **SA Guelcher**, JC Wenke. Development and Evaluation of a Biofilm-Dispersing Scaffold. Orthopaedic Trauma Association (OTA) Annual Meeting, Phoenix, AZ, October 9 - 12, 2013. Oral.
131. CE Nelson, **SA Guelcher**, CL Duvall. Local and Sustained silencing of Proline Hydroxylase 2 Increases Blood Vessel Production in Mice. Biomedical Engineering Society (BMES) Annual Meeting, September 25-28, 2013, Seattle, WA. Oral.
132. JM Page, N Ruppender, S Cannonier, U Dadwal, AR Merkel, SA Guelcher, JA Sterling. Integrin-beta 3 is required for breast tumor response to bone rigidity. ASBMR Annual Meeting, Baltimore, MD, October 4 - 7, 2013. Oral.
133. RJ Guo, S Lu, JM Page, SA Guelcher. Controllable effects of mechanical moduli on osteoblast differentiation of mesenchymal stem cells on polyurethane substrates. AIChE Annual Meeting, San Francisco, CA, November 4 - 8, 2013. Oral.
134. EJ Adolph, CE Nelson, CL Duvall, SA Guelcher. Delivery of diblock copolymer/plasmid DNA polyplexes from polyurethane scaffolds. AIChE Annual Meeting, San Francisco, CA, November 4 - 8, 2013. Poster. Won 2nd Place in MESD Poster Competition.
135. JM Page, NS Ruppender, AR Merkel, U Dadwal, S Cannonier,, SA Guelcher, JA Sterling. Integrin-β3 and TGF-β receptor type II cross-talk induces osteolysis in bone metastatic cancer cells. Cancer-Induced Bone Disease Annual Meeting, Miami, FL, November 6 - 9, 2013. Oral.
136. JR Martin, JM Page, MK Gupta, F Yu, JM Davidson, **SA Guelcher**, CL Duvall. In Vivo Performance of an ROS-degradable Tissue Engineering Scaffold. TERMIS Annual Meeting, Atlanta, GA, November 10 - 13, 2013. Poster.
137. CL Ward, ***R Guo***, JC Wenke, **SA Guelcher**. Development of an Injectable and Settable Polyurethane Cell Delivery System for Bone Regeneration. TERMIS Annual Meeting, Atlanta, GA, November 10 - 13, 2013. Poster.
138. ***AJ Harmata***, CL Ward, S Uppuganti, KJ Zienkiewicz, JS Nyman, JC Wenke, **SA Guelcher**. Effects of surface modification of 45S5 bioactive glass on bioactivity, mechanical, and in vivo remodeling properties of polymeric biocomposites. Materials Research Society Annual Meeting, Boston, MA, December 1 - 6, 2013. Oral.
139. ***AJ Harmata***, CL Ward, S Uppuganti, KJ Zienkiewicz, JS Nyman, JC Wenke, **SA Guelcher**. Effects of surface modification of 45S5 bioactive glass on bioactivity, mechanica, and in vivo remodeling properties of polymeric biocomposites. 5th International Conference on Mechanics of Biomaterials and Tissues, Sitges, SP, December 8 - 12, 2013. Oral.
140. ***AJ Harmata***, KJ Zienkiewicz, D Shimko, K Kalpakci, JS Nyman, SA Guelcher. Effects of surface modification of 45S5 bioactive glass on mechanical and in vivo remodeling properties of polymeric biocomposites. Abstract submitted to 38th International Conference and Expo on Advanced Ceramics and Composites, Daytona Beach, FL, January 26 - 31, 2014.
141. CA Krueger, C Sanchez, **SA Guelcher**, JC Wenke. Development and Evaluation of a Biofilm-Dispersing Scaffold. Abstract submitted to AAOS Annual Meeting, New Orleans, LA, March 11 - 15, 2014. Poster.
142. ***JM Page***, CL Duvall, **SA Guelcher.** Degradable Nanoparticles for pH-dependent Cytosolic Drug Delivery. Abstract to the Society For Biomaterials 2014 Annual Meeting Denver, Colorado, April 16 - 19, 2014. Oral.
143. ***JM Page, AJ Harmata***, **SA Guelcher**. Poraderm: A Fully Degradable Synthetic Cutaneous Wound Treatment. Abstract submitted to the Society for Biomaterials Annual Meeting, Denver, CO, April 16 - 19, 2014. Poster.
144. ***EJ Adolph***, CE Nelson, CL Duvall, **SA Guelcher**. Release of Diblock Copolymer/Plasmid DNA Polyplexes from Polyurethane Scaffolds. Abstract submitted to the Society for Biomaterials Annual Meeting, Denver, CO, April 16 - 19, 2014. Oral.

145. ***R Guo***, CL Ward, JC Wenke, **SA Guelcher**. An injectable and settable cell delivery system for tissue repair derived from in situ chemical polymerization. Abstract submitted to the Society for Biomaterials Annual Meeting, Denver, CO, April 16 - 19, 2014. Oral.
146. ***R Guo, S Lu, JM Page***, **SA Guelcher**. Controllable Effects of Mechanical Moduli on Osteoblast Differentiation of Mesenchymal Stem Cells on Polyurethane Substrates. Abstract submitted to the Society for Biomaterials Annual Meeting, Denver, CO, April 16 - 19, 2014. Poster.
147. ***AD Talley***, KA Kalpakci, ***KJ Zienkiewicz***, JC Wenke, **SA Guelcher**. Space Maintenance and New Bone Formation with Polyurethane Biocomposites in a Canine Saddle Defect. Abstract submitted to the Society for Biomaterials Annual Meeting, Denver, CO, April 16 - 19, 2014. Oral.
148. ***AD Talley***, KN Kalpakci, D Shimko, KJ Zienkiewicz, DL Cochran, **SA Guelcher**. Space maintenance and new bone formation with injectable and settable composite bone grafts in a canine mandibular ridge saddle defect model. Abstracted submitted to the 24th Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures (GRIBOI), May 5 - 7, 2014, Nantes, FR. Oral.
149. CE Nelson, JR Martin, MK Gupta, ***EJ Adolph***, F Yu, JM Davidson, **SA Guelcher**, CL Duvall. Versatile Platform for Sustained Gene Silencing Improves Excisional Wound Healing in Diabetic Rats. Controlled Research Society Annual Meeting, Chicago, IL, July 13 - 16, 2014. Oral. ***Selected for the Outstanding Preclinical Sciences & Animal Health (PSAH) Best Paper Award***.
150. ***UC Dadwal***, ***JM Page***, A Merkel, M Kessler, JA Sterling, **SA Guelcher**. Investigating Osteolytic Bone Destruction in Tumor Induced Bone Disease as a Function of Rigidity using Novel 3D Bone Mimicking Scaffolds. Poster presented at the ASBMR Annual Meeting, Houston, TX, September 12 - 15, 2014.
151. JM Martin, **SA Guelcher**, CL Duvall. Poly(thioketal) polymers and their use in the formation of hydrophobic and hydrophilic cell-degradable tissue engineering scaffolds. Oral presentation at the Biomedical Engineering Society (BMES) Annual Meeting, San Antonio, Texas, October 22-25, 2014.
152. P Thayer, E Tong, L Dahlgren, **SA Guelcher**, AS Goldstein. Mechanical Stimulatin of Cellularized Polyurethane-Collagen Composite Meshes for Connective Tissue Applications. Oral presentation at the Biomedical Engineering Society (BMES) Annual Meeting, San Antonio, Texas, October 22-25, 2014.
153. P Thayer, E Tong, L Dahlgren, **SA Guelcher**, AS Goldstein. Effect of the Mechanical Environment on Connective Tissue Development in Fiber/Hydrogel Composite Meshes. Oral presentation at the AIChE Annual Meeting, Atlanta, GA, November 16 - 21, 2014.
154. RF Dunn, **SA Guelcher**, V Iakovlev. Failure Analysis of Transvaginal Mesh Products – a Biomaterials Perspective Using Materials Science Fundamentals. Oral presentation at the AIChE Annual Meeting, Atlanta, GA, November 16 - 21, 2014.
155. P Thayer, D Plessl, E Tong, S Verbridge, **SA Guelcher**, LA Dahlgren, AS Goldstein. Fiber/Collagen Composites As a Tunable Platform for Guiding Proliferation and Differentiation of Mesenchymal Stem Cells. Oral presentation at the AIChE Annual Meeting, Atlanta, GA, November 16 - 21, 2014.
156. PL Carlisle, DT Silliman, AD Talley, MAJ DI Tucker, COL RG Hale, **SA Guelcher,** PR Brown Baer. LOCALIZED LOW DOSE rhBMP-2 IS EFFECTIVE AT PROMOTING BONE REGENERATION IN A PRE- CLINICAL MANDIBULAR SEGMENTAL DEFECT MODEL. Abstract submitted to the Tissue Engineering and Regenerative Medicine International Society (TERMIS) Annual Meeting, Washington, DC, December 13 - 16, 2014. Poster
157. ***R Guo***, CL Ward, LB Nanney, **SA Guelcher**. An Injectable And Settable Cell Delivery System Derived From In Situ Chemical Polymerization Promote Healing In a Porcine Full-Thickness Excisional Wound Model. Poster presented at the Tissue Engineering and Regenerative Medicine International Society (TERMIS) Annual Meeting, Washington, DC, December 13 - 16, 2014. Poster
158. ***AD Talley***, KN Kalpakci, KJ Zienkiewicz, JC Wenke, **SA Guelcher**. Space Maintenance and New Bone Formation with Polyurethane Biocomposites in a Canine Saddle Defect. Oral presentation at the Tissue Engineering and Regenerative Medicine International Society (TERMIS) Annual Meeting, Washington, DC, December 13 - 16, 2014. Oral

159. V Iakovlev, **SA Guelcher**, R Bendavid. Histological and Ultrastructural Examination of Explanted Meshes Reveals Polypropylene Degradation. United States & Canadian Academy of Pathology (USCAP) Meeting, Boston, MA, March 21 - 27, 2015.
160. ***AD Talley***, KA Kalpakci, KJ Zienkiewicz, **SA Guelcher**. Local Delivery of rhBMP-2 from a Compression-Resistant Graft in a Canine Lateral Ridge Augmentation Model. Society for Biomaterials Annual Meeting, Charlotte, NC, April 15 - 18, 2015. Oral
161. ***AJ Harmata***, S Uppuganti, JS Nyman, **SA Guelcher**. Dynamic compressive fatigue and fracture toughness mechanical properties of 45S5 Bioactive Glass/Polyurethane Biocomposites and Calcium Phosphate/Sulfate Bone Cement. Society for Biomaterials Annual Meeting, Charlotte, NC, April 15 - 18, 2015. Oral
162. ***R Guo***, ***S Lu***, ***JM Page***, A Merkel, JA Sterling, **SA Guelcher**. Crosstalk between Integrin-β1 and BMPR1A mediate matrix regulated MSC osteogenesis. Society for Biomaterials Annual Meeting, Charlotte, NC, April 15 - 18, 2015. Poster
163. ***S Fernando***, JA Sterling, **SA Guelcher**. 3D Printing of Bone-Templated Scaffolds. Society for Biomaterials Annual Meeting, Charlotte, NC, April 15 - 18, 2015. Poster.
164. ***U Dadwal***, ***JM Page***, AR Merkel, M Kessler, JA Sterling, **SA Guelcher**. 3D Printing of Scaffolds with Tunable Modulus and Pore Size for Investigating the Progression of Cancer-Induced Bone Disease *In Vitro*. Abstract submitted to the Society for Biomaterials Annual Meeting, Charlotte, NC, April 15 - 18, 2015. Oral.
165. ***AD Talley***, ***KJ Zienkiewicz***, **SA Guelcher**. Injectable, settable and space-maintaining composite bone grafts for posterolateral fusion. 25th Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures (GRIBOI). Toronto, CA, May 18 - 20, 2015. Oral
166. BR Rogers, RF Dunn, **SA Guelcher**. Characterization of Polypropylene Surgical Mesh For Oxidative Degradation. 37th Annual Symposium on Applied Surface Analysis, Golden, CO, June 2 - 4, 2015. Oral
167. **SA Guelcher**, RF Dunn. Oxidative Degradation of Polypropylene Pelvic Mesh *In Vitro*. Abstract submitted to the International Urogynecological Association 40th Annual Meeting, Nice, France, June 9 - 13, 2015. Oral.
168. J Martin, C Nelson, M Gupta, F Yu, JM Davidson, **SA Guelcher**, CL Duvall. Local Delivery of siRNA from ROS-Degradable Scaffolds to Promote Angiogenesis in Diabetic Wounds. Abstract submitted to the BMES Annual Meeting, Tampa, FL, October 7 -10, 2015. Oral
169. P Thayer, S Verbridge, L Dahlgren, **SA Guelcher**, A Goldstein. Influence of Elastic Moduli of Sparse Aligned Fibers on Bone Marrow Stromal Cells for Ligament Tissue Engineering ApplicationsAbstract submitted to the BMES Annual Meeting, Tampa, FL, October 7 -10, 2015. Poster
170. ***AD Talley***, ***M McEnery***, **SA Guelcher**. Local Delivery of rhBMP-2 from an Injectable, Compression-Resistant Bone Graft in a Canine Lateral Ridge Augmentation Model. Abstract submitted to the International Bone Tissue Engineering Congress, Stuttgart, Germany, October 8 - 10, 2015. Oral
171. ***U Dadwal***, ***R Guo***, A Merkel, ***S Fernando***, D Buenrostro, **SA Guelcher**, **JA Sterling**. Novel 3D model mimics the physical properties of bone to allow for detailed studies of interactions between tumor cells and bone cells. Abstract submitted to the ASBMR Annual Meeting, Seattle, WA, October 9 - 12, 2015. Poster
172. BR Rogers, RF Dunn, **SA Guelcher**. Degradation of Polypropylene Surgical Mesh: An XPS, FTIR, and SEM Study. Abstract submitted to the AVS 62nd International Symposium & Exposition, San Jose, CA, October 18 - 23, 2015.
173. ***AD Talley***, **SA Guelcher**. Local Delivery of rhBMP-2 from an Injectable, Compression-Resistant Bone Graft in a Canine Lateral Ridge Augmentation Model. Abstract submitted to the International Bone Tissue Engineering Congress, Stuttgart, Germany, October 8 - 10, 2015.

174. ***S Lu***, ***R Guo***, **SA Guelcher**. Substrate Modulus and Pore Size of 3D Scaffolds Fabricated By Templated Fused Deposition Modeling Regulate Osteogenic Differentiation. Abstract submitted to the AIChE Annual Meeting, Salt Lake City UT, November 8 - 13, 2015.
175. R Dunn, **SA Guelcher**. Safety Immersion Education Using Vanderbilt's Chemical Process Innovation Center. Abstract submitted to the AIChE Annual Meeting, Salt Lake City UT, November 8 - 13, 2015.
176. ***AD Talley***. **SA Guelcher**. Local Delivery of rhBMP-2 from a Compression-Resistant Graft in a Canine Lateral Ridge Augmentation Model. Abstract submitted to the AIChE Annual Meeting, Salt Lake City UT, November 8 - 13, 2015.

Submitted Abstracts

177. ***JP Vanderburgh***, SA Cannonier, KA Kwakwa, AR Merkel, TA Werfel, CL Duvall, **SA Guelcher**, JA Sterling. Encapsulation of Gli-inhibitors blocks tumor invasion into the bone. Abstract submitted to the Cancer & Bone Society (CABS) Annual Meeting, Rome, Italy, May 14 - 15, 2016.
178. ***UC Dadwal***, ***R Guo***, ***S Lu***, ***JP Vanderburgh***, AR Merkel, K Kwakwa, **SA Guelcher**, JA Sterling. 3D Tissue Engineered Constructs for Modeling Tumor-Induced Bone Disease. Abstract submitted to the Cancer & Bone Society (CABS) Annual Meeting, Rome, ITALY, May 14 - 15, 2016.
179. ***S Lu***, ***MAP McEnery***, K Kalpakci, D Shimko, **SA Guelcher**. Injectable, settable, and resorbable nanocrystalline hydroxyapatite/ polyurethane hybrid polymers with strength comparable to PMMAAbstract submitted to the 26th Interdisciplinary Research Conference on Injectable Osteoarticular Biomaterials and Bone Augmentation Procedures, Shenzhen, CHINA, April 15 - 18, 2016.

5 Patents and Technology Transfer

PATENTS

Issued US and European Patents

1. **SA Guelcher**, JS Kanel. Eastman Chemical Company, assignee. Method for dewatering microalgae with a bubble column. U.S. Patent No. 5,910,254 (foreign equivalents AU6012498, CN1241148). 1998-06-08.
2. **SA Guelcher**, JS Kanel. Eastman Chemical Company, assignee. Method for dewatering algae with a Jameson Cell. U.S. Patent No. 5,776,349 (foreign equivalent AU5802298). 1998-07-07.
3. JS Kanel, **SA Guelcher**. Eastman Chemical Company, assignee. Adsorptive bubble separation methods and systems for dewatering suspensions of microalgae and extracting components therefrom. U.S. Patent No. 5,951,875 (foreign equivalents AU6012598, CN1241149). 1999-09-14.
4. JS Kanel, **SA Guelcher**. Eastman Chemical Company, assignee. Method for rupturing microalgae cells. U.S. Patent No. 6,000,551 (foreign equivalents CN1241209, AU5897898). 1999-12-14.
5. RL Adkins, **SA Guelcher**. Bayer Material Science LLC, assignee. Methacrylates as stabilizers for polymer polyols. US 7,160,975 (EP1624004 (B1)). 2007-01-09.
6. RL Adkins, **SA Guelcher**, JR Charron, JE Hayes. Bayer Material Science LLC, assignee. Low viscosity polymer polyols. US Patent No. 7,179,882 (EP1624006 (A1). 2007-02-20.
7. RL Adkins, **SA Guelcher**. Bayer Material Science LLC, assignee. Novel unsaturated macromers for preformed stabilizers and polymer polyols. EP1675885 (B1) (US20050085613 (A1)). 2008-03-05.
8. **SA Guelcher**, V Patel, JO Hollinger, JE Didier. Degradable polyurethane foams. Carnegie Mellon University, applicant. US 8,318,820 B2. 2012-11-27.
9. S Bhattacharyya, **SA Guelcher**, D Gopal, M Burello. Medtronic, applicant. Isocyanate Manufacture. US 8,552,217. 2013-10-08.

Published US *Patent Applications*

9. **SA Guelcher**, JS Kanel. Eastman Chemical Company, assignee. Method for cross flow microfiltration of microalgae in the absence of flocculating agents. WO9828493 (A1), AU5695598. 1998-07-02.
10. **SA Guelcher**, JS Kanel. Eastman Chemical Company, assignee. Method for deep bed filtration of microalgae. WO9828404 (A1), AU5802398. 1998-07-02.
11. JS Kanel, **SA Guelcher**. Eastman Chemical Company, assignee. Flotation separation methods and systems for dewatering suspensions of microalgae and extracting components therefrom. WO9828082 (A1), CN1241149 (A). 1998-07-02.
12. EJ Beckman, JO Hollinger, BA Doll, **SA Guelcher**, J Zhang. Carnegie Mellon University and University of Pittsburgh, applicants. Biodegradable polyurethanes and use thereof. US20050013793 (A1) (WO2004065450 (A3)). 2005-01-20.
13. **SA Guelcher**, ***AE Hafeman***, *LI Hochhauser*. Vanderbilt University, applicant. Poly(ester urethane)urea foams with enhanced mechanical and biological properties. US 20090130174 (A1) (WO2009026387 (A1)). 2009-05-21.
14. **SA Guelcher**, J England, RL Adkins. Bayer Material Science LLC, assignee. Polymer polyols with improved properties and a process for their production. US20090163613 (A1), (EP2072555 (A1)). 2009-06-25.
15. **SA Guelcher,** JE Didier, JO Hollinger. Biodegradable Polyurethanes. Carnegie Mellon University, applicant. US20090221784 (WO2007123536 (A1)). 2009-09-03.
16. **SA Guelcher**, ***AE Hafeman***, MB Brouner. Vanderbilt University, applicant. Injectable bone/polymer composite bone void fillers. US20100068171 (A1). 2010-03-18.
17. **SA Guelcher**, S Bhattacharyya, ***KJ Zienkiewicz, SA Tanner, JE Dumas***. Vanderbilt University, applicant. Bone/polyurethane composites and methods thereof. US20100112032 (A1). 2010-05-06.
18. **SA Guelcher**, ***J Dumas***. Vanderbilt University, applicant. Polyurethane/bone composition and methods. US20100247672 (A1) (WO2009033102 (A1)). 2010-09-30.
19. **SA Guelcher**, ***JE Dumas***, TM Boyce. Vanderbilt University, applicant. Weight-bearing polyurethane composites and methods thereof. US2010297082 (A1). 2010-11-25.
20. **SA Guelcher**, ***AE Hafeman***. Vanderbilt University, applicant. Release of antibiotic from injectable, biodegradable polyurethane scaffolds for enhanced bone fracture healing. US2011038946 (A1). 2011-02-17.
21. **SA Guelcher,** ***B Li***, ***AE Hafeman*****,** JC Wenke, KV Brown. Vanderbilt University, applicant. Injectable Dual Delivery Allograph Bone/Polymer Composite for Treatment of Open Fractures US 20110236501 (A1). 2011-09-29.
22. **SA Guelcher, *EM Prieto*, *JE Dumas, KJ Zienkiewicz, J Page,*** S Bhattacharyya**.** Vanderbilt University, applicant. Particle/polyurethane Composites and Methods Thereof. US20110237704 (A1), WO2011088157 (A2). 2011-09-29.
23. **SA Guelcher**, ***BH Lee, B Li***. Vanderbilt University, applicant. Encapsulated Cells and Composites Thereof. US Patent Application US 20120183622 (A1). 2012-07-19. (VU1182)
24. **SA Guelcher**, ***JE Dumas***, ***EM Prieto***, K Kalpakci, ***AD Talley***, ***AJ Harmata***, ***KJ Zienkiewicz***. Synthetic Polyurethane Composite. US Patent Application No. US 20130236513 (A1). 2013-09-12.
25. **SA Guelcher**, ***AE Hafeman***, JM Davidson, LM Nanney, ***EJ Adolph***. Polyurethane Composite for Wound Healing and Methods Thereof. US Patent Application No. 20130295081 (A1). 2013-11-07.
26. CL Duvall, **SA Guelcher**, CE Nelson, MK Gupta, ***EJ Adolph***, JM Shannon. Vanderbilt University, applicant Delivery of siRNA from Polyurethane Scaffold. International Patent Application Serial No. WO 2014047524 A1. 2014-03-27 (VU121125).
27. CL Duvall, CE Nelson, J Kintzing, JM Shannon, MK Gupta, **SA Guelcher**, ***EJ Adolph***, JM Davidson. Polymeric Nanoparticles. International Patent Application Serial No. WO 2014066912 A1. 2014-05-01.
28. **SA Guelcher**, JC Wenke, CJ Sanchez Jr, KS Akers, CA Kruger, ***EM Prieto***, KJ Zienkiewicz. Composition with Biofilm Dispersal Agents. US Patent Application N. 20150182667 (A1). 2015-07-02. (VU13029).

29. CL Duvall, **SA Guelcher**, MK Gupta, J Martin, ***JM Page***. Poly(thioketal-urethane) scaffolds and methods of use. International Patent Application Serial No. WO 2014047524 A1. 2014-03-27. (VU12125)

US and European Patent Applications Pending Publication and Review

30. **SA Guelcher**, ***AD Talley***, ***KJ Zienkiewicz***. Injectable Allograft PUR Composite Carrying rhBMP2. US Continuation-in-Part Application No. 13/280,299 filed 2011-10-24 (VU1143).

TECHNOLOGY COMMERCIALIZATION

PEURegen, LLC, Nashville, TN

Co-Founder	2013 - present
Director of Research	2013 - present
NCIIA E-Team Participant Stage I, II, III	2013 - present
Position in Open Minds 2013 Competition VilCap VentureWell Health Boston	2014
Accelerator participant (finished 5th of 12)	2014
Accepted to Launch TN Phase 0/00 Program for grant writing	2014
Accept to Life Science TN Venture Forum 2014 competition	2014

Medical Technology Enterprise Consortium

Participant	2015 - present

CONSULTING

Eastman Chemical Company, Kingsport, TN

Limited Service Employee	1995 - 1997

Osteotech, Eatontown, NJ

Consultant	2005 – 2010
Member of Polymer Technology Advisory Board	2005 – 2010

Medtronic, Inc., Memphis, TN

Consultant	2011 - present

Material Answers, Boston, MA

Consultant	2007

McLane Law Firm, Concord, NH

Consultant	2008 – 2010

Polymer and Chemical Technologies, LLC, Nashville, TN

Consultant	2013 - 2014

Guelcher Consulting, LLC, Thompsons Station, TN

Owner	2014 - present

6 Teaching

POST-DOCTORAL SCHOLARS ADVISED

1. ***Shaun Tanner***. 2009 - 2010. Currently at MED Institute, Inc.
2. ***Baek-Hee Lee***. 2010 - 2012. Currently at Samsung

GRADUATE STUDENTS ADVISED

Graduated PhD Students

1. ***Tiffany Rau***. 2006 – 2007. *Biochemical Effects of Rapamycin and Sodium Butyrate in the Enhancement of MAb Production in the CRL 1606 Hybridoma Cell Line*. (originally a student of R. Robert Balcarcel). Graduated May 2007. Currently at the Center of Fermentation Excellence, Eli Lilly.
2. ***Andrea E. Hafeman***. 2005 - 2010. *Biodegradable Polyurethane Scaffolds with Local Delivery of Bioactive Molecules for Tissue Regeneration*. Graduated May 2010. Currently Senior Manager, Global Medical Affairs at Baxter Healthcare.
3. ***Bing Li***. May 2006 – 2010. *Biodegradable Polyurethane Scaffolds and Delivery Systems for Regeneration of Bone Tissue.* Graduated May 2010. Currently a Materials Scientist at GE Global Research.
4. ***Jerald Dumas***. 2005 – 2010. *Allograft Mineralized Bone Particle/polyurethane Composites for Bone Tissue Engineering*. Graduated December 2010. Currently a Post-doctoral Research Associate at Georgia Tech.
5. ***Nazanin S. Ruppender***. 2006 – 2011. *Matrix Mechanical Properties and the Invasive Potential of Metastatic Cancer*. Graduated May 2011. Currently an Editor at American Journal Experts.
6. ***Margarita Prieto***. 2008 – 2013. *Injectable polyurethane composites for bone defects with tunable mechanical, processing and in vitro biological properties.* Graduated December 2013. Currently at Abbot Laboratories.
7. ***Jonathan M. Page***. 2010 - 2014. *Design of Novel Polyurethane Biomaterials for Synthetic Extracellular Matrices*. Graduated May 2014. Currently at Microport.
8. ***Elizabeth Adolph***. 2009 - 2014. *Injectable Polyurethane Scaffolds with Delivery of Biologics for Skin Wound Healing.* Graduated May 2014. Currently at Baylor University Medical Center.
9. ***Ruijing Guo***. 2010 - 2015. *Cell delivery with polyurethane scaffolds for wound healing.* Graduated May 2015. Currently at Bayer MaterialScience.
10. ***Drew Harmata***. 2010 - 2015. *Injectable, Settable Polyurethane and Bioactive Glass Biocomposite for Bone remodeling in weight-bearing applications*. Graduated May 2015. Currently at IQuity Labs.

Graduated MS Students

1. ***Andrew C. Exton***. 2009 - 2011. *Mechanical Properties of Biodegradable Weight-bearing Allograft Bone/polyurethane and Calcium Phosphate/polyurethane Composites*. Graduated August 2011.

PhD Candidates

1. ***Anne Talley***. 2011 - present. *Injectable Polyurethane Scaffolds for the Healing of Bone Defects*. Anticipated Graduation May 2016.
2. ***Ushashi Dadwal***. 2013 - present. *Studying Cancer-Induced Bone Disease by Developing an Artificial Bone Analogue System*. Anticipated Graduation December 2015.
3. ***Sichang Lu***. 2012 - present. *Three-dimensional Model of Osteoblast-Osteoclast-Tumor Co-culture System.* Anticipated Graduation May 2017.

PhD Pre-candidates

4. ***Madison McEnery.*** 2014 - present. Anticipated Departmental Exam August 2015.
5. ***Tom Spoonmore***. 2015 - present. Anticipated Departmental Exam August 2015.
6. ***Joe Vanderburgh***. 2015 - present. Anticipated Departmental Exam August 2015.

Medical Emphasis Students

1. ***Shanik Fernando***. Medical Emphasis Student, 2014.

Undergraduate Research Students Advised

Carl Plumley, Justin Smith, Lance Hochhauser, Michelle Brouner, Phil Masui, James O'Keefe, Thomas Davis, David Harris, Patrick Boyer, Michael Skoumal, Mallory Smyth, Sally Ingham, Erica von Stein, Kassandra Mast, Brian Cheng, Jose Garza, Graham Rucker, Nick Gould, Cody Dykes, Will Braun, Mollie Maples

High School Research Students Advised (through Vanderbilt School for Science and Math)

Armond Moyo, Anna-Claire Brakefield, Laura Moribe, Michelle Lu, Lilly Kwan

COURSES TAUGHT

1. Fall 2005. Kinetics (ChE 225). Enrollment 27. Required.
2. Spring 2006. Polymer Science and Engineering (ChE 290). Enrollment 10. Elective.
3. Fall 2006. Kinetics (ChE 225). Enrollment 27. Required.
4. Spring 2007. Polymer Science and Engineering (ChE 290). Enrollment 13. Elective.
5. Fall 2007. Kinetics (ChE 225). Enrollment 29. Required.
6. Spring 2008. Bioprocess Engineering (ChE 283). Enrollment 7. Elective.
7. Fall 2008. Introduction to Engineering (ES140). Enrollment 28. Required.
8. Spring 2009. Chemical Reaction Engineering (ChBE 225). Enrollment 29. Required.
9. Fall 2009. Introduction to Engineering (ES140). Enrollment 25. Required.
10. Fall 2009. Bioprocess Engineering (ChBE 283). Enrollment 29. Required.
11. Spring 2010. Chemical Reaction Engineering (ChBE 225). Enrollment 41. Required.
12. Fall 2010. Introduction to Engineering (ES140). Enrollment 25. Required.
13. Spring 2011. Chemical Reaction Engineering (ChBE 225). Enrollment 52. Required.
14. Fall 2011. Introduction to Engineering (ES140). Enrollment 31. Required.
15. Spring 2012. Chemical Reaction Engineering (ChBE 225). Enrollment 51. Required.
16. Spring 2013. Chemical Reaction Engineering (ChBE 225). Enrollment 57. Required.
17. Fall 2013. Molecular and Cell Biology for Engineers (ChBE 281). Enrollment 46. Required.
18. Spring 2014. Chemical Reaction Engineering (ChBE 225). Enrollment 54. Required.
19. Fall 2014. Chemical Process Design (ChBE 233). Enrollment 52. Required.
20. Spring 2015. Chemical Process Design (ChBE 234). Enrollment 52. Required.
21. Fall 2015. Introduction to Engineering (ES140). Enrollment 30. Required.
22. Fall 2015. Design Seminar (ChBE 297). Enrollment 50. Required.
23. Spring 2016. Chemical Engineering Design Projects (ChBE 234). Enrollment 50. Required.

7 Service

REVIEWING SERVICE

Grant Review Panels

1. Orthopaedic Extremity Trauma Research Program. 2007
2. CDMRP. 2012
3. NSF-DMR. 2007 - present.
4. NIH Special Emphasis Panels. 2014 - present.
5. AAAS. 2014

Journal Reviewer

Acta Biomaterialia
Advances in Wound Care
Journal of Biomaterials Science: Polymer Edition
Journal of Controlled Release

Biomacromolecules
Biomaterials
Biomaterials Science
Biomedical Materials
Cancer Letters
Clinical Orthopaedics and Related Research
Industrial Engineering and Chemistry Research
Journal of Biomaterials Applications
Journal of Biomedical Materials Research Part A
Journal of Biomedical Materials Research Part B
Journal of Investigative Dermatology
Journal Materials Chemistry
Nature Protocols
Pharmaceutical Research
Polymer
Polymer International
Soft Materials
Tissue Engineering
Small

SERVICE TO THE SCIENTIFIC COMMUNITY

Membership in Professional Societies

1. Member, American Institute of Chemical Engineers (AIChE). 2000 – present.
2. Member, Society for Biomaterials (SFB). 2003 - present.
3. Member, Interdisciplinary Research Society for Bone and Joint Injectable Biomaterials (GRIBOI). 2010 - present.
4. Member, American Chemical Society (ACS). 2011 - present.
5. *Forum* reporter. Drug Delivery Special Interest Group (SIG), Society for Biomaterials, 2013 - 2015.
6. Chair. Dental/Craniofacial Biomaterials Special Interest Group (SIG, Society for Biomaterials, 2015.

Conference Organization

1. AIChE Session Chair, Area 8a Biomaterials. 2006 – present.
2. AFIRM I All-hands meeting Session Chair. 2010
3. Reviewer. Society for Biomaterials Annual Meeting Abstracts. 2008 - present
4. Session Co-organizer: Beyond PMMA Bone Cement. GRIBOI Annual meeting. 2013.
5. Co-moderator. BMP2, The Bone Growth Factor: Panel Discussion. Society for Biomaterials Annual Meeting. 2013.
6. AFIRM II Investigators Meeting Session Chair. 2014 - present
7. AFIRM II Synergy Meeting Planning Committee. 2014
8. Society for Biomaterials Session Co-organizer: “Next Generation Biomaterial and Drug Delivery Technologies for Wound Healing.” 2015
9. Session Co-Organizer/Participant: Court is in Session: Will Transvaginal Mesh Win or Lose? Workshop at the International Urogynecological Association (IUGA) 40th Annual Meeting, Nice, France. June 9 - 13, 2015.
10. Discussion Leader. NSF Multiscale/3D Printing Cement Workshop. Vanderbilt University, Nashville, TN. July 16 - 17, 2015

Advisory Committees

1. AFIRM I Standards Development Committee. 2010 - 2011.
2. Biomedical Engineering Department Advisory Board. University of Memphis. 2012 - 2014.
3. Scientific Advisory Board. Interdisciplinary Research Society for Bone and Joint Injectable Biomaterials (GRIBOI). 2014 - present.
4. Advancing Regenerative Medicine Manufacturing Know-how and Capacity: Core Capabilities & Shared Facilities Committee. Armed Forces Institute of Regenerative Medicine II (AFIRM). 2014 - present.

5. Medical Technology Enterprise Consortium (MTEC) aligned with the US Army Medical Research and Materiel Command. 2015 - present.
6. Scientific Advisory Board. TENSIVE S.r.l., Milano, Italy. 2015 - present

SERVICE TO THE UNIVERSITY

Department

1. Faculty Advisor, AIChE Student Chapter. 2005 - present.
2. Member, ChBE Undergraduate Curriculum Committee. 2005 - 2011, 2014 - present
3. Member, ChBE Graduate Committee. 2011 - 2013

School

1. Member, VUSE Career Committee. 2008 - 2014
2. Member, Entrepreneurship Task Force. 2012 - 2014
3. Advisor, Society for Biomaterials Student Chapter, 2013 - 2014
4. Member, VUSE Design Committee. 2014 - present

University

1. University Chemical Safety Committee. 2009 - present.
2. Vanderbilt Center for Technology Transfer and Commercialization Faculty Advisory Committee. 2012 - present.
3. Faculty Senate. 2012 - 2015.
4. Technology Review Committee. 2012 - 2014

LITERATURE

Author	Name	Journal Citation
Abbas Shobeiri S, et al	The anatomy of midurethral slings and dynamics of neurovascular injury	Int Urogynecol J (2003) 14: 185-190
Abed H, Rahn DD, et al	"Incidence and Management of Graft Erosion, Wound Granulation, and Dyspareunia Following Vaginal Prolapse Repair with Graft Materials: A Systematic Review "	The International Urogynecology Journal,22:789-98,22-Mar-11
Achimsky, L.	Kinetic Study of the Thermal Oxidation of Polypropylene.	Polymer Degradation and Stability 57:231-240 (1997).
Alajmo F	Polypropylene Suture Fracture2	Ann Thorac Surg 1985 39.4: 400
Alexander	Histopathologic host response to polypropylene-based surgical mesh materials in a rat abdominal wall defect model	2363-80A. JBMR 24: 621-37, 1990.
Aldrete V	Polpropylene Suture Fracture	Ann Thorac Surg 1984 Mar; 37(3):264
Altman AJ, Gorn RA, et al	The breakdown of polypropylene in the human eye: is it clinically significant?	Ann Ophthalmol 1986 May; 18(5) 182-5
Altman D, Väyrynen T, et al	Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse.	New England Journal of Medicine,364:1826-36, 5/12/2011
An, YH	Concise Review of Mechanisms of Bacterial Adhesion to Biomaterial Surfaces	J Biomed Mater Res (Appl Biomater) 1998;43:338-48
Anderson	Cellular interactions with biomaterials: in vivo cracking of pre-stressed Pellethane	
Anderson H	Utilization of Adipose Tissue Biopsy and Characterizing Human Halogenated Hydrocarbon Exposure	Environmental Health Perspectives, Voloume 60, pp. 127-131
Anderson JM, et al	Foreign Body Reaction to Biomaterials	Semin Immunol 2008 April; 20(2): 86-100
Apple DJ, Mamalis N, et al	Biocompatibility of implant materials: a review and scanning electron microscopic study	J Am Intraocul Implant Soc 1984 Winter; 10(1):53-66
Bachman, S, Ramshaw, B	Prosthetic Material in Ventrial Hernia Repair: How Do I Choose?	Surg Clin N Am 88 (2008) 101-112
Barber, M., et al	Single-Incision Mini-Sling Compared With Tension-Free Vaginal Tape for the treatment of Stress Urinary Incontinence	Obstetrics & Gynecology, Vol. 119, No. 2, Part 1 (Feb 2012)
Barbolt TA	Biology of polypropylene/polygiactin 910 grafts	Int Urgynecol J (2006) 17; S26-S30
Bazi, T. et al.	Polypropylene Midurethral Tapes Do Not Have Similar Biologic and Biomechanical Performance in the Rat.	European Urology 51(2007): 1364-1375
Bendavid R	Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain	International Journal of Clinical Medicine, 2014, 5, 799-810

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6/29/2010	Clinical Study Report A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prolift +M Pelvic Floor Repair System as a Device for Pelvic Organ Prolapse	ETH.MESH.00080795	ETH.MESH.00080924
??/??/07	Prolift +M IFU	ETH.MESH.00081133	ETH.MESH.00081139
11/9/2010	11/9-11/2010 AAGL Meeting PPT Presentation.	Eth.Mesh.00107688	
11/9/2011	AAGL Las Vegas meeting brochure	ETH.MESH.00107688	ETH.MESH.00107688
	TVT Professional Education Program	ETH.MESH.00156909	ETH.MESH.00156938
??/??/06	No bigger than your palm - brochure	ETH.MESH.00158289	ETH.MESH.00158293
	Memorandum re Copy review submission compliance	ETH.MESH.00159473	ETH.MESH.00159473
5/4/2007	Gynecare TVT Secur System: Key Technical Points	ETH.MESH.00163952	ETH.MESH.00163960
4/18/2006	CER Weisberg - Laser Cut Mesh	ETH.MESH.00167104	ETH.MESH.00167110
2/8/2002	Design Validation Strategy Version 1	ETH.MESH.00199408	ETH.MESH.00199413
11/24/2005	Team conference call notes	ETH.MESH.00208897	ETH.MESH.00208897
11/10/2009	Mini TVT-O Team Meeting	Eth.Mesh.00211038	Eth.Mesh.00211041
11/10/2009	Mini TVT-O Team Meeting Agenda	ETH.MESH.00211038	ETH.MESH.00211041
1/8/2002	Barbolt memo to D'Aversa re Biocompatibility Risk Assessment for Prolene	ETH.MESH.00220333	ETH.MESH.00220336
5/14/2001	TVT-O Design History Book 5 of 7	ETH.MESH.00222779	ETH.MESH.00223267
	TVT-O Design History Book 5 of 7	Eth.Mesh.00222779	
5/14/2001	TVT-O Design History Book 1 of 7	ETH.MESH.00259047	ETH.MESH.00259514
	TVT-O Design History Book 1 of 7	Eth.Mesh.00259047	
12/15/2003	Product Design Safety Assessment Revision 2	ETH.MESH.00259473	ETH.MESH.00259503
5/29/2003	Study description Chart	ETH.MESH.00260020	ETH.MESH.00260021
4/14/2003	Smith,D email chain re Mulberry update	ETH.MESH.00260591	ETH.MESH.00260592
0/0/2003	Email re: lack of clinical data	Eth.Mesh.00260591	
6/9/2003	O'Bryan S email re Mulberry stage gate action item closed	ETH.MESH.00261584	ETH.MESH.00261585
	PPT Presentation titled “The Science of What’s Left Behind: Evidence & Follow-Up of Mesh Use for SUI.”	Eth.Mesh.00271641	
	Nick Franco Naples, FL Presentation: The Science of "What's Left Behind"... Evidence & Follow-Up of Mesh Used for SUI	ETH.MESH.00271641	ETH.MESH.00271641
11/21/2005	Email re: GREAT NEWS FOR TVT LASER CUT MESH!	Eth.Mesh.00301741	Eth.Mesh.00301742
11/21/2005	Lamont D email chain re Great News for TVT Laser Cut Mesh	ETH.MESH.00301741	ETH.MESH.00301742
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh Risk Analysis Summary	ETH.MESH.00302105	ETH.MESH.00302106
2/20/2007	Lamont D email chain re Complaint Summaries	ETH.MESH.00303084	ETH.MESH.00303085
3/5/2008	Lamont D email chain re Gynemesh issue	ETH.MESH.00303944	ETH.MESH.00303945

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4/29/2008	Lamont D email chain re Post Launch Reviews	ETH.MESH.00304013	ETH.MESH.00304014
		ETH.MESH.00308747	
3/3/2008	Robinson D email chain re Quality issue with a batch of gynemesh	ETH.MESH.00328895	ETH.MESH.00328901
	- DFMEA	ETH.MESH.00335080	ETH.MESH.00335080
12/18/2008	Lisa B email chain re TVT Patient Brochure Fair Balance EPI Changes	ETH.MESH.00339083	ETH.MESH.00339084
02/??/02	5 Years of Proven Performance	ETH.MESH.00339437	ETH.MESH.00339442
4/1/2009	Email re: TVT-Mini Clinical Support.	Eth.Mesh.00346227	
4/1/2009	Lisa B email re TVT-Mini clinical support	ETH.MESH.00346277	ETH.MESH.00346277
	Excel Spreadsheet of Pain associated with TVT-O.	Eth.Mesh.00354725	
	Spreadsheet re TVT-O pain	ETH.MESH.00354725	ETH.MESH.00354725
??/??/10	pg from Minimally invasive synthetic suburethral sling operation for SUI in women	ETH.MESH.00355087	ETH.MESH.00355087
		ETH.MESH.00360799	
	Revision Hx for PR800-012 Rev 11	ETH.MESH.00363605	ETH.MESH.00363625
1/28/1998	510(k) clearance letter	ETH.MESH.00371496	ETH.MESH.00371594
2/1/2006	Global Regulatory Strategy GYNECARE TVT - Laser Cutting Project	ETH.MESH.00394544	ETH.MESH.00394553
5/6/2005	London Brown A email re Laser-cut Mesh	ETH.MESH.00526473	ETH.MESH.00526474
6/23/2006	St. Hilaire P email chain re LCM - Launch Strategy EMEA	ETH.MESH.00526484	ETH.MESH.00526487
5/22/2007	Smith D email chain re TVT Secur EU Experts meeting - feedback & future action	ETH.MESH.00527832	ETH.MESH.00527836
9/27/2010	Shah N email chain re Textile supplier	ETH.MESH.00528621	ETH.MESH.00528626
11/18/2003	Wesiberg Memo to File re Mesh Fraying for TVT Devices	ETH.MESH.00541379	ETH.MESH.00541380
10/18/2010	Caro-Rosado L email chain re Lab results orf Mesh roping evaluation	ETH.MESH.00544657	ETH.MESH.00544658
5/18/2006	Cantimbuhan R email re design transfer checklist dicussion, 05/16/06	ETH.MESH.00554680	ETH.MESH.00554680
2/15/2006	Flatow J email chain re DVer protocol for particle loss	ETH.MESH.00584291	ETH.MESH.00584292
6/6/2006	Fournier H re New Standards for Urethral Slings	ETH.MESH.00584488	ETH.MESH.00584494
6/6/2006	Fournier H re New Standards for Urethral Slings	ETH.MESH.00584491	ETH.MESH.00584497
2/19/2004	Email thread re: Prolene Mesh.	Eth.Mesh.00584714	
2/19/2004	Kammerer G email chain re Prolene Mesh	ETH.MESH.00584714	ETH.MESH.00584715
4/19/2004	Kammerer G email re Ultrasonic Slitting of Prolene Mesh for TVT	ETH.MESH.00584811	ETH.MESH.00584813
3/10/2006	Next Generation Mesh Discussion Agenda	ETH.MESH.00585672	ETH.MESH.00585673
5/9/2006	Email re: Particle Loss on TVT	Eth.Mesh.00585802	
5/9/2006	Kammerer G email re Particle loss of TVT	ETH.MESH.00585802	ETH.MESH.00585802
6/12/2006	Kammerer G email chain re TVT LCM - particle loss (reimbursement submission)	ETH.MESH.00585842	ETH.MESH.00585843

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1/20/2006	Kammerer G email chain re TVT - TVT-O specifications	ETH.MESH.00585906	ETH.MESH.00585909
2/13/2006	Kammerer G email chain re TVM discussions	ETH.MESH.00585937	ETH.MESH.00585939
3/28/2007	Performance Evaluation Technical Report	ETH.MESH.00593165	ETH.MESH.00593189
	PPT Slides "TVT Abbrevo U.S. Launch Overview."	Eth.Mesh.00632655	
	U.S. Launch Overview	ETH.MESH.00632655	ETH.MESH.00632655
		ETH.MESH.00684368	
12/19/2005	Mahar K mail chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
12/19/2005	Mahar K email chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
12/21/2005	Honjnoski P email chain re CER - LCM	ETH.MESH.00700344	ETH.MESH.00700345
10/5/2006	Hernandez J email re TVT LCM Early EU Feedback	ETH.MESH.00746204	ETH.MESH.00746208
??/??/06	Product Pointer	ETH.MESH.00746209	ETH.MESH.00746209
	Surgeon Evaluation Questions for Laser Cut Mesh	ETH.MESH.00746210	ETH.MESH.00746212
11/9/2010	TVT Classif IFU Revision Project Design Requirements Waiver Rationale Memo	ETH.MESH.00748213	ETH.MESH.00748213
5/15/2008	Prolift +M FDA Clearance Letter	ETH.MESH.00748451	ETH.MESH.00748803
8/23/2005	Final Report, PSE Accession Number 05-0395, Project Number 67379	ETH.MESH.00749504	ETH.MESH.00749517
3/9/2006	Interim Report Test and Control ARticle Material Characterization Program	ETH.MESH.00750766	ETH.MESH.00750769
11/21/2005	Process Qualification Completion Report Version 1	ETH.MESH.00752863	ETH.MESH.00752893
	RMR - TVT-S	ETH.MESH.00752921	ETH.MESH.00752925
	Risk Management Report Revision History for RMR-0000021	ETH.MESH.00752928	ETH.MESH.00752932
	TVT Secur Harm/Hazards Table	ETH.MESH.00752933	ETH.MESH.00752934
12/17/2008	Osman R email chain re 2008 Budget Spend	ETH.MESH.00772228	ETH.MESH.00772229
12/17/2008	Osman R email chain re Updated Fair Balance for TVT Brochure	ETH.MESH.00772231	ETH.MESH.00772232
	Presentation: Gynecare TVT Secur Project Overview PLT REview	ETH.MESH.00826057	ETH.MESH.00826067
4/12/2007	Thunder Meeting Minutes	ETH.MESH.00832555	ETH.MESH.00832556
1/22/2008	Thunger Meeting Minutes	ETH.MESH.00832562	ETH.MESH.00832564
	Arnaud, Robinson presentation: Characteristics of Synthetic Materials Used in Prolapse and Incontinence Surgery	ETH.MESH.00838428	ETH.MESH.00838469
8/31/2007	Robinson D email chain re Asking TVT Complication? - Fraying	ETH.MESH.00844331	ETH.MESH.00844335
8/31/2007	Robinson D email Chain re Asking TVT Complication? - Fraying	ETH.MESH.00844341	ETH.MESH.00844344
5/27/2008	Risk Benefit Analysis TVT-S	ETH.MESH.00853802	ETH.MESH.00853806
1/22/2004	Presentation: Sales Training Launch Meeting Gynecare TVT Obturator System	ETH.MESH.00857821	ETH.MESH.00857923
	Luscombe presentation: Top Ten Reasons to Pursue Gynecare TVT Obturator System	ETH.MESH.00857891	ETH.MESH.00857893

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	Internal Dan Smith memo – Gynecare board discussed risk of no clinical prior to launch, will proceed as no clinical needed	Eth.Mesh.00858080	
	Smith D Memo re Gynecare Board risk discussion before launch	ETH.MESH.00858080	ETH.MESH.00858081
06/??/03	Gynecare R&D Monthly Update - June	ETH.MESH.00858092	ETH.MESH.00858093
3/4/2003	Gynecare R&D Monthly Update - March	ETH.MESH.00858094	ETH.MESH.00858095
	Gynecare R&D Monthly Update -- May	ETH.MESH.00858096	ETH.MESH.00858097
6/3/2003	Mulberry Weekly Meeting Minutes for 06/03/2003	ETH.MESH.00858175	ETH.MESH.00858177
	London Brown Memo to Smith re Mechanical Cut vs Laser Cut Mesh Rationale	ETH.MESH.00858252	ETH.MESH.00858253
	Smith D Memo TVT Secur Lessons Learned Review	ETH.MESH.00858636	ETH.MESH.00858641
	Where the market is heading	ETH.MESH.00858891	ETH.MESH.00858891
6/1/2009	Smith D email chain re Sample medio TVTO	ETH.MESH.00860142	ETH.MESH.00860144
6/2/2003	Smith D email re My notes from the Thursday evening presentation 5/22/03 and Friday's surgery	ETH.MESH.00862727	ETH.MESH.00862728
2/27/2004	Email re: 2 TVT Complaints concerning allegedly brittle mesh	Eth.Mesh.00863391	Eth.Mesh.00863393
2/27/2004	Smith D email chain re 2 TVT Complaints concerning allegedly brittle mesh	ETH.MESH.00863391	ETH.MESH.00863393
3/9/2004	Emails re: Complaint TVTO	Eth.Mesh.00863405	Eth.Mesh.00863407
3/9/2004	Luscombe B email chain re Complaint TVT-O	ETH.MESH.00863405	ETH.MESH.00863407
7/24/2003	Smith D email chain re TOVT developments	ETH.MESH.00864101	ETH.MESH.00864102
8/15/2001	Luscombe B email chain re Aug 11 program	ETH.MESH.00864131	ETH.MESH.00864133
5/5/2004	Smith D email chain re TVT-O	ETH.MESH.00864407	ETH.MESH.00864408
9/8/2004	Smith D email chain re Ongoing TVT-O Action Items	ETH.MESH.00864490	ETH.MESH.00864492
9/14/2004	Smith D email chain re Ongoing TVT-O Action Items	ETH.MESH.00864493	ETH.MESH.00864496
3/2/2004	Email re: Reminder on BLUE mesh!	Eth.Mesh.00865322	Eth.Mesh.00865323
3/2/2004	Owens C email chain re Reminder on BLUE mesh	ETH.MESH.00865322	ETH.MESH.00865323
8/14/2007	Thunder meeting minutes	ETH.MESH.00869908	ETH.MESH.00869909
		ETH.MESH.00869977	
6/2/2006	Expert Meeting Minutes - Meshes for Pelvic Floor Repair	ETH.MESH.00870466	ETH.MESH.00870476
6/6/2006	Ethicon Expert Meeting Meshes for Pelvic Floor Repair	Eth.Mesh.00870466	
8/13/2006	London Brown, A email chainre LIGHTning clinical strategy	ETH.MESH.00870481	ETH.MESH.00870482
2/8/2006	Yale M email chain re MHRA request - TVT (change to dying process)	ETH.MESH.00874032	ETH.MESH.00874035
		ETH.MESH.00876900	
1/18/2008	Zaddem V email re 510(k) mesh data	ETH.MESH.00906445	ETH.MESH.00906445
4/13/2005	Sunoco, Inc MSDS	ETH.MESH.00918015	ETH.MESH.00918019

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	MSDS for Sunoco C4001 Polypropylene Homopolymer.	Eth.Mesh.00918015	
1/1/1970	St Hilaire P re Bidirectional Elasticity Statement	ETH.MESH.00922443	ETH.MESH.00922446
	Weisberg M Final Draft CER	ETH.MESH.00998286	ETH.MESH.00998291
12/13/2005	St. Hilaire email chain re Clinical Expert Report Laser Cut Mesh	ETH.MESH.00998292	ETH.MESH.00998293
6/22/2006	Gadot, Harel email re LCM - Launch Strategy EMEA	ETH.MESH.00998347	ETH.MESH.00998347
4/18/2006	Weisberg M and Robinson D CER	ETH.MESH.00998349	ETH.MESH.00998355
3/9/2007	Smith D email chain re Draft of latest "cookbook"" after Germany trip	ETH.MESH.01000323	ETH.MESH.01000329
6/4/2013	Professional Education Index	ETH.MESH.01000449	ETH.MESH.01000452
12/19/2006	Robinson D email chain re TVT-S Cookbooks	ETH.MESH.01000731	ETH.MESH.01000733
2/8/2005	Final Report Ethicon Study No S04/2-2-1 A 3 month -re-clinical trial to assess the fixation force of a new TVT (TVTx) in the sheep model	ETH.MESH.01037530	ETH.MESH.01037545
	TVT and TVT-O Risk Management Report Rev. 1	Eth.Mesh.01066916	Eth.Mesh.01066932
	TVT and TVT-O RMR Rev 1	ETH.MESH.01066916	ETH.MESH.01066932
	Smith, Lond Brown presentation: Gynecare TVT Secur	ETH.MESH.01150009	ETH.MESH.01150059
		ETH.MESH.01154031	
6/6/2001	Barbolt Memo to Ciarroca re Biocompatibility Risk Assessment for the TVT-L Device	ETH.MESH.01159961	ETH.MESH.01159962
1/16/2001	Dormier D email chain re Corporate Product Characterization December Monthly Report	ETH.MESH.01160507	ETH.MESH.01160518
	Marketing Brochure - Make Data and Safety Your Choice	ETH.MESH.01186068	ETH.MESH.01186072
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny visit	ETH.MESH.01202101	ETH.MESH.01202103
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny Visit	ETH.MESH.01202101	ETH.MESH.01202103
11/14/2008	Hinoul presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203998
11/14/2008	Hinoul Austria Presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203957
	TVT Abbrevo Risk Management Report Rev. 1	Eth.Mesh.01212090	Eth.Mesh.01212099
	TVT-Abbrevo RMR Rev 1	ETH.MESH.01212090	ETH.MESH.01212099
	Hutchinson Final Report An Exploratory 91-Day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats	ETH.MESH.01217925	ETH.MESH.01217959
	Revision History for dFMEA0000242	ETH.MESH.01218019	ETH.MESH.01218019
	TVT Laser Cut Mesh Risk Management Report Rev. 1	Eth.Mesh.01218099	Eth.Mesh.01218103
	TVT RMR Rev 1	ETH.MESH.01218099	ETH.MESH.01218103
4/5/2007	State of Knowledge in "mesh shrinkage"--What we know	Eth.Mesh.01218361	Eth.Mesh.01218367
4/5/2007	Spychaj K memo re Shrinking meshes	ETH.MESH.01218361	ETH.MESH.01218367
3/19/2003	Final Test Report - Prolene	ETH.MESH.01218446	ETH.MESH.01218449

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5/9/2006	Flatow J email chair re Particle loss on TVT	ETH.MESH.01219629	ETH.MESH.01219630
3/20/2006	CPC-2006-0014, Completion Report for the Design Verification of TVT Laser Cut Mesh Particle Loss at 50%Elongation	Eth.Mesh.01219984	
3/20/2006	Flatow Completion Report for Design Verification of TVT Laser Cut Mesh	ETH.MESH.01219984	ETH.MESH.01219994
10/14/2003	Kammerer G re Technical data on competitive meshes from Europe	ETH.MESH.01220710	ETH.MESH.01220711
5/4/2006	Kammerer G email re New Standards for Urethral Slings	ETH.MESH.01221024	ETH.MESH.01221025
3/9/2006	Kammerer G email chain re Elongation properties of LCM	ETH.MESH.01221618	ETH.MESH.01221619
3/7/2006	Weisberg, Robinson Clinical Expert Report	ETH.MESH.01221735	ETH.MESH.01221740
	Elongation Characteristics of Laser Cut Prolene Mesh for TVT	Eth.mesh.01222075	Eth.mesh.01222079
2/28/2003	Cirellli - Histological evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model	ETH.MESH.01222617	ETH.MESH.01222654
	Nilsson Podcase Transcript	ETH.MESH.01228079	ETH.MESH.01228084
2/5/2008	Robinson CER Gynecare Prolift+M	ETH.MESH.01259495	ETH.MESH.01259509
6/28/2002	Lawler T email re Polypropylene Mesh	ETH.MESH.01264260	ETH.MESH.01264260
2/17/2011	Zaddem V email re mesh pore size - tissue compliance and contraction	ETH.MESH.01264497	ETH.MESH.01264498
3/14/2008	Risk Management Report (Legacy) for TVT and TVT-O	Eth.Mesh.01265223	Eth.Mesh.01265239
	RMR TVT and TVT-O Rev 1	ETH.MESH.01265223	ETH.MESH.01265239
	TVT and TVT-O Risk Management Report Rev. 2	Eth.Mesh.01268264	Eth.Mesh.01268277
	RMR for TVT and TVT-O Revision History for RMR-0000044	ETH.MESH.01268264	ETH.MESH.01268277
	TVT Laser Cut Mesh Risk Management Report Rev. 2	Eth.Mesh.01310061	Eth.Mesh.01310065
	TVT Laser Cut RMR Rev 2	ETH.MESH.01310061	ETH.MESH.01310065
	TVT Laser Cut Mesh Risk Management Report Rev. 3	Eth.Mesh.01310476	Eth.Mesh.01310481
	TVT RMR Rev 3	ETH.MESH.01310476	ETH.MESH.01310481
		ETH.MESH.01316489	
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01316727	ETH.MESH.01316765
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01317508	ETH.MESH.01317613
4/25/2002	DDSA Re-Evaluation for TVT	ETH.MESH.01317510	ETH.MESH.01317514
7/12/2000	TVT-2 needles Introducer Revision 8	ETH.MESH.01317515	ETH.MESH.01317524
5/14/2001	TVT-O Design History Book 2 of 7	ETH.MESH.01317769	ETH.MESH.01318358
	TVT-O Design History Book 2 of 7	Eth.Mesh.01317769	
5/14/2001	Target Sheet DH1017-DH1019(bk5)	ETH.MESH.01318359	ETH.MESH.01318831
	TVT-O Design History Book 4 of 7	Eth.Mesh.01318359	
5/14/2001	TVT-O Design History Book 6 of 7	ETH.MESH.01318832	ETH.MESH.01319499
	TVT-O Design History Book 6 of 7	Eth.Mesh.01318832	
5/14/2001	TVT-O Design History Book 7 of 7	ETH.MESH.01319500	ETH.MESH.01320123

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	TVT-O Design History Book 7 of 7	Eth.Mesh.01319500	
6/18/2007	Volpe, Meier presentation: Exploratory Program "Thunder" A Material designed for pelvic floor	ETH.MESH.01405166	ETH.MESH.01405166
1/3/2009	Potential Failure Mode and Effects Analysis Chart Process FMEA	ETH.MESH.01407837	ETH.MESH.01407857
3/21/2006	Product Specification TVT-S Revision B	ETH.MESH.01410044	ETH.MESH.01410047
	Test Report No. B0086/02 Test for local effects after implantation	ETH.MESH.01424246	ETH.MESH.01424290
7/11/2001	91-day intramuscular tissue reaction study conducted in rats.	Eth.Mesh.01425079	ETH.MESH.01425113
2/27/2006	Design Validation Report TVTSDVLPRD2	ETH.MESH.01592178	ETH.MESH.01592188
	Ethicon Memo re: Prolene Pore Size	Eth.Mesh.01752532	
	Ethicon R&C Memo re Mesh design argumentation issues	ETH.MESH.01752532	ETH.MESH.01752535
	Clinical Expert Report ULTRAPRO	ETH.MESH.01760853	ETH.MESH.01760861
12/15/2006	Arnaud A email re TVT-S Cookbooks	ETH.MESH.01770534	ETH.MESH.01770534
	TVT-Secur: "Hammock" position - description for right-handed surgeon	ETH.MESH.01770535	ETH.MESH.01770540
	TVT-Secur: "U" Position - description for right-handed surgeon	ETH.MESH.01770541	ETH.MESH.01770546
12/20/2006	Robinson emai chainl re TVT-S Cookbooks	ETH.MESH.01784428	ETH.MESH.01784435
	LCM CER	Eth.mesh.01784823	Eth.mesh.01784828
1/17/2010	Hinoul, P email chain re +M relaxation	ETH.MESH.01785259	ETH.MESH.01785260
0/0/2010	Hinoul email reporting meeting with Klosterhalfen	Eth.Mesh.01785259	
8/17/2010	Clinical Expert Report TVT Abbrevo	ETH.MESH.01795909	ETH.MESH.01795929
	Abbrevo Clinical Expert Report	Eth.Mesh.01795909	
	Draft Smith presentation: The Mesh Story	ETH.MESH.01805985	ETH.MESH.01806002
4/25/2002	Test Report - Prolene	ETH.MESH.01808729	ETH.MESH.01808741
12/14/2004	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices	ETH.MESH.01809080	ETH.MESH.01809081
12/14/2004	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices (BE-2004-1641)	ETH.MESH.01809080	ETH.MESH.01809081
	London-Brown A Memto to Parisi, Mahar re VOC on new Laser Cut TVT Mesh	ETH.MESH.01809082	ETH.MESH.01809083
11/29/2004	Parisi P email re TVT Laser cut mesh business case	ETH.MESH.01811758	ETH.MESH.01811758
12/10/2004	Bell S email chain re VOC on Laser cut mesh	ETH.MESH.01811770	ETH.MESH.01811772
6/20/2003	Elbert K email chain re Design Control	ETH.MESH.01814371	ETH.MESH.01814372
	Work Instruction for New Product Design Control	ETH.MESH.01814384	ETH.MESH.01814400
8/17/2004	Burns J email chain re TVT-O Dr. Feagins case follow up	ETH.MESH.01815505	ETH.MESH.01815513
6/17/2003	Smith D email chain re Discussion 11th June 2003	ETH.MESH.01815611	ETH.MESH.01815613
	Spreadhseet mesh characeristis	ETH.MESH.01816988	ETH.MESH.01816989
5/9/2006	Mesh Development Timeline	Eth.Mesh.01816990	
??/??/06	Mesh development timeline	ETH.MESH.01816990	ETH.MESH.01816990

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7/31/2007	Thunder Meeting minutes	ETH.MESH.01819505	ETH.MESH.01819506
7/5/2009	Robinson Literature Review - Pelvic Organ Prolapse Repair Procedures	ETH.MESH.01819528	ETH.MESH.01819572
10/18/2006	Smith D email chain re TVT-Secur	ETH.MESH.01822361	ETH.MESH.01822363
3/25/2004	Zaddem V email chain re disclosure questions	ETH.MESH.01988643	ETH.MESH.01988644
	Test Method Applicability/Suitability Rev History for FM-0000020	ETH.MESH.01992234	ETH.MESH.01992237
2/16/2011	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02010834	ETH.MESH.02010855
12/2/2004	Rousseau R email re umbilical hernia surgery sales contacts	ETH.MESH.02011199	ETH.MESH.02011199
2/23/2007	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair brochure	ETH.MESH.02017152	ETH.MESH.02017158
03/??/01	Hellhammer B Meshes in Pelvic Floor Repair Findings from literature reivew and interviews with surgeons	ETH.MESH.02017169	ETH.MESH.02017190
		ETH.MESH.02017169	
	Biocompatability of Prosima components final draft insert into 510k	ETH.MESH.02020023	ETH.MESH.02020024
4/13/2005	Sunco C4001 Polypropylene Homopolymer MSDS	ETH.MESH.02026591	ETH.MESH.02026595
??/??/03	Marketing brochure Gynemesh PS A New Mesh for Pelvic Floor Repair Early Clinical Experience	ETH.MESH.02053629	ETH.MESH.02053632
		ETH.MESH.02053629	
5/21/2009	Protocol Study Title: A Phase 2 Study to Evaluate the Safety ad Efficiary of the Fibrin Pad Hemostatic Dressing in Trauma Patients Undergoing Re-Laprotomy after Initial Damages Control Surgery	ETH.MESH.02059212	ETH.MESH.02059232
6/22/2001	Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes	ETH.MESH.02089392	ETH.MESH.02089399
8/8/2006	Holste Barbolt Mesh chara sign page	ETH.MESH.02091873	ETH.MESH.02091873
	Physician Post-Operative Questionnaire	ETH.MESH.02106803	ETH.MESH.02106803
6/18/2008	KOL Interview: Carl G. Nilsson	ETH.MESH.02126222	ETH.MESH.02126227
10/6/2008	Barbolt, T. Mechanisms of Cytotoxicity for TVT Polypropylene	Eth.Mesh.02134271	
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5/26/2000	Corporate Product Characterization Product Safety Profile for PROLENE Mesh	Eth.Mesh.02134274	
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12/5/2003	Biocompatibility Risk Assessment for the Gynecare TVT	Eth.Mesh.02134312	
12/5/2003	Memo re Biocompatibility Risk Assessment for the Gynecare TVT Obturator	ETH.MESH.02134312	ETH.MESH.02134314
	TVT Secur System Design Validation Report	ETH.MESH.02135955	ETH.MESH.02135968

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06/??/09	Intermediate Report - Prolapse Mesh Explants 6/2009	ETH.MESH.02157879	ETH.MESH.02157880
3/26/2008	Robinson D email chain re UP	ETH.MESH.02170708	ETH.MESH.02170709
6/24/2003	Toddywala R email re Project Mulberry	ETH.MESH.02180737	ETH.MESH.02180737
3/29/2004	Memo from Jean de Leval, MD	Eth.Mesh.02180759	
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11/12/2004	Email re: Mesh Fraying: Dr. EBERHARD Fraying: DR. EBERHARD letter	Eth.Mesh.02180826	Eth.Mesh.02180827
11/12/2004	Menneret D email chain re Mesh Fraying: Dr. Eberhard letter	ETH.MESH.02180826	ETH.MESH.02180827
11/10/2004	Sibylle B Memo to Menneret D re TVT blue	ETH.MESH.02180828	ETH.MESH.02180830
10/18/2004	Translation of PD Doctor Eberhard's letter	ETH.MESH.02180833	ETH.MESH.02180833
4/22/2003	Burkley D email chain re Pore size request	ETH.MESH.02183533	ETH.MESH.02183536
4/3/2009	Rathore O email chain re Analytical characterization - Optimization of STructure	ETH.MESH.02184435	ETH.MESH.02184436
4/27/2010	Flint J email chain re surface area	ETH.MESH.02185004	ETH.MESH.02185004
2/16/2011	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02185584	ETH.MESH.02185605
10/16/2007	Arnold, K email chain re LIghtning - Mesh Strength Design Requirement	ETH.MESH.02195798	ETH.MESH.02195799
2/5/2008	Robinson CER Gynecare Prolift +M	ETH.MESH.02198933	ETH.MESH.02198947
6/10/2008	Batke B email chain re Bisphenol A (BPA) - Question	ETH.MESH.02207388	ETH.MESH.02207389
	Spreadsheet re Mesh characteristics	ETH.MESH.02212840	ETH.MESH.02212842
08/??/10	Presentation: TOPA & SCION PA Alignment	ETH.MESH.02218268	ETH.MESH.02218292
	Presentation Script	ETH.MESH.02219162	ETH.MESH.02219164
	Rule 26 Expert Report of Howard Jordi, PhD in Carolyn Lewis case	ETH.MESH.02219202	ETH.MESH.02220048
	Meshes/Devices Chart	ETH.MESH.02227368	ETH.MESH.02227368
	Meshes/Devices	ETH.MESH.02227368	ETH.MESH.02227368
1/13/2011	TVT-O Marketing video	ETH.MESH.02229061	ETH.MESH.02229061
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2/21/2003	Dion, D email re Prolene additives and exposure	ETH.MESH.02268618	ETH.MESH.02268618
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	TVT IFU	ETH.MESH.02340331	ETH.MESH.02340335
2/11/2005	TVT IFU	ETH.MESH.02340471	ETH.MESH.02340503
10/13/2008	TVT IFU	ETH.MESH.02340504	ETH.MESH.02340567
12/16/2005	TVT-S IFU	ETH.MESH.02340568	ETH.MESH.02340755
3/7/2005	TVT-O IFU 03/07/20050-005/19-2005	ETH.MESH.02340756	ETH.MESH.02340828
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1/7/2004	TVT-O IFU (1/7/2004-3/4/2005)	ETH.MESH.02340829	ETH.MESH.02340901
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5/12/2010	TVT-O IFU (05/12/2012-present)	ETH.MESH.02340902	ETH.MESH.02340973
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5/25/2005	TVT-O IFU (05/25/2005-04/29/2008)	ETH.MESH.02340974	ETH.MESH.02341046
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	Prosima IFU	ETH.MESH.02341407	ETH.MESH.02341410
4/23/2013	IFU Index and Production Bates Range Chart	ETH.MESH.02341954	ETH.MESH.02341954
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6/16/2008	Design Requirements Matrix Prolift+M /Lightning	ETH.MESH.02915783	ETH.MESH.02915797
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2/16/2011	Holste email chain re Prosima +M clin strat	ETH.MESH.03146492	ETH.MESH.03146493
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	Chart of pain associated with TVT-O.	Eth.Mesh.03454726	
10/12/2005	Holloway ltt Ethicon France re fraying	ETH.MESH.03535750	ETH.MESH.03535750
11/22/2005	Process Qualification Completion Report	ETH.MESH.03648795	ETH.MESH.03648810
	Revision History for FM-0000167	ETH.MESH.03652924	ETH.MESH.03652955
	Table re Raw data for force to achieve elongation	ETH.MESH.03658980	ETH.MESH.03658980
9/10/2009	Ng W email chain re August 2009 YTD Travel & Consulting spend	ETH.MESH.03699545	ETH.MESH.03699546
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	Spreadsheet product characteristics	ETH.MESH.03751168	ETH.MESH.03751175
	Table comparing meshes	ETH.MESH.03751168	ETH.MESH.03751168
5/18/2010	TVT Abbrevo Launch Planning Stage Gate PLT brochure	ETH.MESH.03753682	ETH.MESH.03753682
	Abbrevo Launch PPT Wanted to meet unmet demand of less persistent pain with Obturator	Eth.Mesh.03753682	
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9/18/2005	Weisberg M email chain re clinical expert report	ETH.MESH.03905619	ETH.MESH.03905621
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12/19/2006	Robinson D email chain re TVT Secur	ETH.MESH.03921499	ETH.MESH.03921500
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1/16/2007	Buchon X email chain re French data on TVT Secur	ETH.MESH.03922953	ETH.MESH.03922953
1/10/2007	Robinson D email chain re Report from Austria	ETH.MESH.03922966	ETH.MESH.03922967
6/6/2000	Hellhammer B - Meshes in Pelvic Floor Repair Findings from literature review and conversations/interviews with surgeons	ETH.MESH.03924557	ETH.MESH.03924586
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1/16/2007	"Confidential: History of TVT-O" by Axel Arnaud	Eth.Mesh.03932909	Eth.Mesh.03932911
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1/29/2009	Email re: TVT IFUs on tape extrusion, exposure and erosions	Eth.Mesh.04093125	
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3/5/2012	CDMA Meeting Minutes - 2012	ETH.MESH.04548236	ETH.MESH.04548242
3/20/2012	Hinoul P email chain re Polypropylene Mesh	ETH.MESH.04937874	ETH.MESH.04937876
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2/28/2006	Corporate Product Characterization Plan for Gynecare TVT-S	ETH.MESH.04939027	ETH.MESH.04939035
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	Holste presentation: Lightweight Mesh Developments	ETH.MESH.04941016	ETH.MESH.04941049
4/18/2005	Klosterhalfen B email re Ultrapro vs Prolene Soft Mesh	ETH.MESH.04945496	ETH.MESH.04945496
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2/3/2012	Cheng, K email chain re a few things	ETH.MESH.05107016	ETH.MESH.05107017
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11/7/2005	Patire-Singer W email chain re TVT Records	ETH.MESH.05220458	ETH.MESH.05220464
4/7/2006	TVT IFU	ETH.MESH.05222673	ETH.MESH.05222705
7/1/2010	TVT Abbrevo 510(k) Clearance and Application	Eth.Mesh.05224295	
7/1/2010	TVT Abbrevo 510(k) Clearance and Application	ETH.MESH.05224295	ETH.MESH.05224391
9/8/2000	TVT-IFU	ETH.MESH.05225354	ETH.MESH.05225385
	TVT IFU	ETH.MESH.05225380	ETH.MESH.05225384
	Meier presentation: Mesh Properties - How important are they?	ETH.MESH.05237872	ETH.MESH.05237910
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	Operating Procedure for Failure Modes and Effects Analsis	ETH.MESH.05432198	ETH.MESH.05432224
	Applied Science & Technology Performance Evaluation Abstract Biaxial testing of two commonly used Ethicon meshes	ETH.MESH.05442973	ETH.MESH.05442975
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5/30/2011	Spreadsheet listing microporous, medium and macroporous meshes	Eth.Mesh.05479535	
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	Analytical Characterization PPT Presentation	ETH.MESH.11488705	ETH.MESH.11488724
3/31/2011	Phillips K email re Prosima+M	ETH.MESH.11790162	ETH.MESH.11790162
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8/10/1990	Ten Year In Vivo Suture Study - Five Year Report	ETH.MESH.12729337	ETH.MESH.12729350
10/10/1990	Five Year Data for Ten Year PROLENE Study	Eth.Mesh.12729337	ETH.MESH.12729350
9/30/1987	Ethicon Prolene study of human explants	Eth.Mesh.12831391	ETH.MESH.12831404
6/15/1982	Melveger Memo re Crack Depth in Explanted Porlene Polypropylene Sutures	ETH.MESH.12831405	ETH.MESH.12831406
11/12/1987	Prolene Explants Study Meeting Minutes.	Eth.Mesh.12831407	ETH.MESH.12831408
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5/3/2013	Prosima CER	ETH.MESH.12897617	ETH.MESH.12897678
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9/17/2013	Hinoul email chain re TVT Secur CER for Risk analysis meetings	ETH.MESH.13456293	ETH.MESH.13456299
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??/??/1987	Prolene Explant Lab Notebook Pages and Images	ETH.MESH.15406846	ETH.MESH.15406856
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15406846	Eth.Mesh.15406999
N/A	Prolene Explant Lab Notebook Pages and Associated Documents	ETH.MESH.15406846	ETH.MESH.15406999
1/20/1988	List of Explants	ETH.MESH.15406978	
3/23/1983	Matlaga memo to Lunn re Prolene Microcracks	ETH.MESH.15955438	ETH.MESH.15955473
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15955438	Eth.Mesh.15955473
11/13/1984	Memo to McDivitt J re Fourier Transform-Infared Examination of Prolene Microcrack and Photo-Oxidized Polypropylene	ETH.MESH.15958336	ETH.MESH.15958395
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3/17/1982	Microscopic Examination of Prolene Suture and Dacron Graft Returned for Norfolk Surgical Group, Ltd (human retrieval).	ETH.MESH.15958396	ETH.MESH.15958399
11/7/1984	Prolene Polypropylene Suture Explant from Dr. Drewes	Eth.Mesh.15958405	ETH.MESH.15958407
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3/25/1983	Examination of 5/0 and 6/0 Cardiovascular Prolene Sutures Explanted after 2 to 6 years Implantation.	ETH.MESH.15958410	ETH.MESH.15958432

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8/4/1984	Examination of Ends of PREP and Prolene Sutures Reported to have Broken in Animals.	Eth.Mesh.15958433	Eth.Mesh.15958444
3/11/1985	Prolene Microcrack Experiments	ETH.MESH.15958445	ETH.MESH.15958541
11/5/1984	Prolene Microcracking	ETH.MESH.15958452	ETH.MESH.15958469
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15958470	Eth.Mesh.15958477
	Prolene Explant Lab Notebook Pages and Images	Eth.Mesh.15958478	Eth.Mesh.15958524
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	Explant Images	ETH.MESH.15958525	ETH.MESH.15958532
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2/7/2008	Kahlson H email chain re Conversion to Laset Cut TVT	ETH.MESH.16416002	ETH.MESH.16416004
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7/6/2011	Email re: pore classification	Eth.Mesh.5337217	
	Chart re Prolene weight and pore size	Eth.Mesh.9671620	
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??/??/06	GPS for Pelvic Floor Repair	ETH-00289	ETH-00294
??/??/04	Prolift IFU	ETH-00295	ETH-00300
1/22/2008	Lisa Memo re question for updated IFU	ETH-01754	ETH-01756
2/28/2005	Everett J Summary Memo for Revision C of the Gynecare PROLIFT Device Design Safety Assessment	ETH-03531	ETH-03567
2/28/2005	Everett Memo re Summary for Revision C of the Gynecare Prolift Device Safety Assessment	ETH-03534	ETH-03570
	PR602-003 Appendix VI - Device Design Safety Assessment Form	ETH-03558	ETH-03558
		ETH-03568	
4/7/2008	Pelekis Memo to Samon re Risk Assessment for Laser Ccutting of D'Art Gynemesh PS Implants	ETH-03883	ETH-03889
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1/14/2005	Owens Clinical Expert Report Gynecare Prolift	ETH-07152	ETH-07158
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??/??/06	Stop coping. Start Living Patient Brochure	ETH-10187	ETH-10202
1/18/2005	Brown K email chain re Proposal for work with CBAT	ETH-18761	ETH-18763
	IFU illustrations	ETH-65881	ETH-65881
6/14/2006	Bonet G email chain re Mesh Microns	ETH-83454	ETH-83454
1/26/2006	Porosity Measurement of AMS Intepro Mesh	ETH-83788	ETH-83788
4/14/2006	Regina A email chain re TSM presentations	HMESH.ETH.00108021	HMESH.ETH.00108024
8/31/2009	Rauso J email chain Re shrinkage	HMESH.ETH.00110207	HMESH.ETH.00110208
6/12/2012	Fuchte L email re Ultrapro article in newspaper	HMESH.ETH.00129489	HMESH.ETH.00129490

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	Nylon MSDS	HMESH_ETH_00660369	HMESH_ETH_00660411
11/1/1988	Santonox R Antioxidant MSDS	N/A	N/A
6/26/2007	DLTDP MSDS	N/A	N/A
10/5/2010	DLTDP MSDS (2)	N/A	N/A
4/24/2012	Calcium Stearate MSDS	N/A	N/A
5/21/2013	Calcium Stearate MSDS (2)	N/A	N/A
	MSDS for Calcium Stearate	N/A	
	MSDS for Dilauralthiodipropionate (DLTDP)	N/A	
	MSDS for Santonox R	N/A	
	MSDS for Procol LA-10	N/A	
	MSDS for Copper phthalocyanate (CPC) Pigment	N/A	
	Sunoco MSDS 2006	N/A	
	Sunoco MSDS 2004	N/A	
	Marlex MSDS 2011	N/A	
	Marlex MSDS 2001, 2003, 2004, 2007, 2008	N/A	
	In Vitro degradation testing and related documents on polypropylene in collaboration with Dr. Russell Dunn	N/A	
6/22/2006	Gadot, H EMEA Launch Strategy		

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Mesh Litigation
Retainer and Fee Schedule
January 1, 2015- December 31, 2015

Fee Schedule

Labor	**Cost**	
Ph.D. Chemical Engineer – Research and Analysis		
Half day	$ 1,250	
Full day	$ 2,500	
Ph.D. Chemical Engineer – Report Preparation		
Short Report	$ 7,500	
Medium Report	$ 10,000	
Long Report	$ 12,500	
Ph.D. Chemical Engineer – Expert Deposition and Court Testimony		
Half day	$ 2,000	
Full day	$ 4,000	
Ph.D. Chemical Engineer – Travel		
Half day	$ 1,000	
Full day	$ 2,000	
Ph.D. Chemical Engineer – Deposition/Trial Preparation	$ 7,500	
Expense Items		
Travel		Air travel, rental car and hotel billed at cost. Mileage per diem rate for personal car.
Travel Meals		Per diem or at cost

Payment Terms and Late Fee

Payment is due within 30 days of each invoice. Interest at a rate of 1.5% per month will be billed on all invoices over 45 days past due.

Daubert-Frye Challenges

It will be the responsibility of the Client to immediately notify the Consultant and the Firm if such a challenge is anticipated or has been filed in order that the Firm may participate in formulating an appropriate response. Any costs related to such a challenge shall be the responsibility of the Client. If the Firm or the Consultant determines that the Client's response to the challenge is inadequate, the Firm and the Consultant shall have the right to immediately terminate services in the case upon written notice to Client.